COMPARATIVE STUDY OF EXTRA AMNIOTIC SALINE INFUSION THROUGH INTRACERVICAL BALLOON CATHETER AND PROSTOGLANDIN E2 GEL FOR INDUCTION OF LABOUR

DISSERTATION SUBMITTED FOR

M.S OBSTETRICS AND GYNECOLOGY

BRANCH II

MADRAS MEDICAL COLLEGE

CHENNAI

THE TAMIL NADU Dr. M.G.R MEDICAL UNIVERSITY

CHENNAI

APRIL 2016

BONAFIDE CERTIFICATE

This is to certify that this dissertation entitled **" COMPARATIVE STUDY OF EXTRA AMNIOTIC SALINE INFUSION THROUGH INTRACERVICAL BALLOON CATHETER AND PROSTAGLANDIN E2 GEL FOR INDUCTION OF LABOUR"** has been done by Dr. V.VIJAYALAKSHMI, Post Graduate in M.S (Obstetrics and Gynaecology) under my overall supervision and guidance at Govt. Hospital for Women and Child Health, Institute of Obstetrics and Gynaecology, Madras Medical College, Chennai in partial fulfillment of regulations of TamilNadu Dr.M.G.R. Medical University for the award of M.S. Degree in Obstetrics and Gynecology.

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DECLARATION

I, Dr. V.VIJAYALAKSHMI solemnly declare that the dissertation tiltled **"COMPARATIVE STUDY OF EXTRA AMNIOTIC SALINE INFUSION THROUGH INTRACERVICAL BALLOON CATHETER AND PROSTAGLANDIN E2 GEL FOR INDUCTION OF LABOUR"** has been prepared by me. I also declare that this bonafide work or a part of this work was not submitted by me or any other person for any award, degree or diploma to any other university board either in India or abroad.

This is submitted to The Tamil Nadu Dr. MGR Medical University, Chennai in partial fulfillment of the rules and regulations for the award of M.S degree Branch II Obstetrics and Gynaecology to be held in April 2016.

PLACE: **Dr.V.Vijayalakshmi**

DATE:

ACKNOWLEDGEMENT

I am very thankful to **Prof. Dr. R. Vimala, MD.,** Dean, Madras Medical College for her kind permission to carry out this study at Institute of Obstetrics and Gynaecology, Chennai.

I express my sincere gratitude and thanks to **Prof.Dr.Baby Vasumathi, MD.,DGO.,** Director, Institute of Obstetrics and Gynecology, Chennai for her guidance.

I sincerely extend my thanks to my guide, **Prof. Dr. Prema Elizabeth, MD., DGO.,** for her encouragement and guidance in conducting the study.

I am extremely thankful to **Prof. Dr. Krishnaveni, MD DGO** for helping me choose the topic and **Prof. Dr. Usha Rani MD DGO** for her valuable suggestions and for having helped me to complete my studies.

I am very grateful to **Assistant Prof.Dr.Kavitha, MD.,DGO** and **Dr. Shanthi, MD.,DGO,** Institute of Obstetrics and Gynaecology, Chennai for their valuable guidance and suggestions in the executing this study.

My sincere thanks to all other Assistant Professors and fellow postgraduates for their help during the course of this study.

My special thanks to my sister **V.Vaishanavi B.tech., MBA** and my parents for helping me and being a huge moral support.

Lastly and most importantly, I am indebted to all my patients who willingly participated in this study.

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CONTENTS

COMPARTIVE STUDY OF EXTRA-AMNIOTIC SALINE INFUSION THROUGH INTRACERVICAL BALLOON CATHETER & PGE2 GEL FOR LABOUR INDUCTION

ABSTRACT

BACKGROUND:

For a majority of women , labour starts spontaneously at term /near term. But now in modern obstetrics , labour induction is mandatory because of medical /obstetric complications

Since no methods is free from complications, this study is carried out with the aim of finding out the effective method of induction with least complications

AIM OF STUDY

The study is carried out to assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour.

OBJECTIVES OF THE STUDY

- ✓ To study the effect of cervical ripening
- ✓ To study the oxytocin augmentation need
- ✓ To see the effect on the labour outcome
- ✓ To study the response difference in primi and multi
- ✓ To assess the maternal and fetal outcome

Study Centre

The study was undertaken in the Institute of Obstetrics and Gynecology, Egmore, Chennai.

Study design

Prospective randomized control study conducted between August 2014 - August 2015

Sample size

200 antenatal mothers admitted in the hospital were included in this study.

Inclusion criteria

1. Singleton pregnancy
2. Cephalic presentation
3. Absence of infection
4. Bishop score <5
5. Term / Post term pregnancies
6. Intact fetal membrane

Exclusion criteria

1. Low lying placenta
2. Malpresentation
3. Maternal infection
4. Rupture of membranes
5. Maternal comorbid illnesses like Gestational diabetes, Heart disease, Chronic kidney disease

Induction indications

- Post EDD pregnancies
- oligohydroamnios
- Intra uterine growth restriction
- Gestational hypertension

METHODOLOGY

Before inducing EDD confirmed with regard to LMP, Regularity of menstrual cycles, Early Ultrasonogram scan. 100 Antenatal mother with Bishop score <5 induced with extra amniotic normal saline (40-60ml/ hr for 6 hrs)& PGE2 gel.

Induction labour interval , induction delivery interval, rate of cesarean deliveries, maternal & fetal outcome were compared

RESULT

Both the groups were induced with almost similar Bishop score initially. The mean Bishop score at 0 hrs, 6 hours, 12 hours was significantly increased in patients induced with Extra amniotic saline infusion compared to PGE2 gel group.

Majority of the patients induced with Extra amniotic saline infusion established active labour within 6 hrs whereas in PGE2 gel active labour established in 6-12 hrs.Extra amniotic saline infusion was found to be more effective in causing cervical ripening than PGE2 gel. Oxytocin use in Extra amniotic saline infusion was only 43% whereas in PGE2 gel group was about 72%. More number of patients in the PGE2 gel group required oxytocin for further progress of labour.

76% of patients delivered vaginally in the Extra amniotic saline infusion group whereas only 67% had labour natural in the PGE2 gel group. Incidence of Cesarean delivery was significantly lower in the Extra amniotic saline infusion when compared to the PGE2 gel group.

CONCLUSION

Cervical ripening was more effective in the Extra amniotic saline infusion group when compared to PGE2 group.Mean Induction to active labour interval (ILI) was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.Mean Induction to delivery interval (ILI) was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.Oxytocin usage was lower in the Extra amniotic saline infusion group when compared to PGE2 gel group.Fetal and Maternal outcome were better in the Extra amniotic saline infusion group than PGE2 gel group.Extra amniotic saline infusion was found to be more effective, cheaper and readily available method for cervical ripening and for induction of labour.

KEYWORDS

Extra amniotic saline infusion, PGE2 gel group, Oxytocin.

INTRODUCTION

- For a majority of women, labour starts spontaneously at term or near term. In modern obstetrics induction of labour is mandatory , because of medical or obstetric complications of pregnancy.

Definition of lnduction of labour

- Stimulation of regular uterine contractions in a viable pregnancy before the onset of labour using mechanical or pharmacological methods in order to generate progressive cervical dilatation and subsequent delivery after fetus maturity.

- Induction of labour is as old as Soraners of Greece, who was the first person to induce labour in 100 A.D. From the days of Soraners to the modern days of obstetrics , induction of labour has gone through different methods over different periods by different people. Steamens started inducing labour electively for the convenience of obstetricians or the expectant mother, the indication being for social one.

- Induction is accepted as an option in the management of selected cases of high risk pregnancies in which the continuation of pregnancy is likely to affect adversely the maternal health or the perinatal outcome.

- Ideally the patient to be induced should be term or near term with adequate pelvis , favorable cervix & with a viable fetus.

- Failed induction is termed when the uterus to fail to contract after recommended attempts of stimulation , or the uterus contracts abnormally , or cervix does not dilate, or the fetus is in jeopardy.

- Stimulation of uterine contractions by means of non-pharmacological agents administered intracervically to the patients with the aim of starting labour constitutes "**Mechanical induction of labour"**

- Stimulation of uterine contractions by means of pharmacological agent given to the patients by any route with the aim of inducing labour is "Medical induction of labour".Oxytocin is the drug that is being employed with considerable success for induction of labour for many years. It has been associated with uterine hypertonus fetal bradycardia, also fluid retention in patients with eclampsia, hypertension, heart & kidney disease.

- Unripe cervix was one of the biggest drawbacks in induction of labour. There was revolutionary change after introduction of prostaglandins.

- Bygdemans first used prostaglandins & their use in induction of labour is very effective and well appreciated. Cole etal., showed that under proper conditions ,the advantage of inducing labour outweighs its disadvantages.

- Though induction of labour is aimed at vaginal delivery, increased risk of caesarean section. Individual variation is more and hence each patient needs to be viewed in the context of her past obstetrical history and complications in the present pregnancy before deciding on the mode of induction.

Risks of induction of labour

1. **OPERATIVE DELIVERY:** In both primi and muti iol increases risk of caesarean section. About 3 fold increase in primi compared to those labouring spontaneously. In muti it is doubled from 3.4% to 8.5%
2. **UTERINE HYPERCONTRACTILITY:** any agent used in IOL can over stimulate the uterus leading to prolonged or tonic uterine contractions, fetal compromise and abnormal FHR patterns.
3. **UTERINE RUPTURE:** rare but occurs in patients with uterine scar like caesarean section or uterine perforation
4. **FAILED INDUCTION:** rates of failed induction is about 3%
5. **IATROGENIC PREMATURITY**
6. **PAIN**

No method of induction is free from complications, aim of this study is to find the effective method with least complications. The study was undertaken with the objective of observing difference in the responses of mechanical & medical induction of labour. The Study was conducted in Institute of Obstetrics & Gynecology, Egmore Chennai.

REVIEW OF LITERATURE

- Induction of labour is unavoidable in modern obstetrics because of the maternal obstetrical and medical complications.

- The outcome of successful induction depends on the perfect balance between the hazards of meddling and risks of avoidable complications by non – intervention

- Methods of induction of labour are listed here, some of which are historical interest only.

- HAMILTON tried stripping of membrane in 1810. This was used mainly in cephalo pelvic disproportion and breech presentation to preserve hind water. This method is still in practice though not for the same indications.

- In 1820- BRUNNING HAUSEN introduced spongy tests to dilate the cervix and thereby induce labour.

- In 1843 SCHREIBER stimulated labour electrically. In 1846 KIWISCH used hot vaginal douche. In the same year COHEN used the extra amniotic fluid administration for labour induction.

- In 1865 WILSON used laminaria tents. Assumed probably function through the disturbance of chorio amniotic decidual interphase and thereby bring lysosomal destruction and prostaglandin synthesis.

- In 1935 VANEULER, introduced the term prostaglandins. In 1971, KARIM & SHARMA first induced labour with use of oral PGE2. Since then a large number of reports have appeared in literature, evaluating the efficacy of oral PGE2 for induction of labour .

- Oral PGE2 induces normal uterine contraction and soften the cervix , thereby decreasing the resistance of the cervix to dilation.

- Cervical dilatation with a ballon catheter was introduced to BARNES by WOODMAN in 1863. Since then several modifications of this method are reported. One method is the infusion of extra amniotic normal saline and is referred as EASI.

- In 1989 SCHREYER etal ., found that extra amniotic saline infusion resulted in greater increase in cervical dilatation in less time when compared to vaginal prostaglandin E2.

- SHERMAN in 1996 summarized the results of 13 trials with ballon catheters and concluded that , with or without saline infusion , the method cause rapid improvement in Bishop score and shortened labours.

- VENGALIL and colleagues in 1998 proved that extra amniotic saline infusion resulted in greater increase in Bishop score compared with 50 ug misoprostol administered vaginally every 4 hours.

- HELMIN & MOLLER In 1998 reported catheter infusion to be efficacious for cervical ripening than prostaglandin E2 gel.

- GOLDMAN & WIGTON in 1999 demonstrated a significantly higher Bishop score with extra amniotic catheter infusion compared with intracervical dinoprostone.

- GUINN & colleagues in 2000 compared induction of labour with intracervical dinoprostone , laminaria plus intravenous oxytocin and extra amniotic saine infusion. Significantly proved that induction to delivery interval was less with extra amniotic saline infusion than laminaria or dinoprostone gel.

- BUCCELLATO and associates in 2000 proved that there was greater increase in Bishop score with extra amniotic saline infusion when compared with 50ug of misoprostol.

- GUINN DAVIES , JK JONES, SULLIVAN L, WOLF D in 2004 conducted randomized control study for labour induction and compared foley catheter with concurrent oxytocin and foley cather with extra amniotic saline infusion and proved saline infusion was effective.

- SHARAMI, MILANI in 2005 conducted randomized control trial compared cervical ripening with PGE2 gel & extra amniotic saline infusion and demonstrated that extra amniotic saline infusion was effective.

- KARJANE NW, BROCK EC in 2006 done a prospective study for induction of labour using foley ballon with and without amniotic saline infusion and showed with saline infusion induction is more effective.

- SAIMA QAMAR, ADELLAR in 2012 conducted a comparative study of PGE2 gel, PGE2 pessary and extra amniotic saline infusion with oxytocin for induction of labour and found saline infusion have greater increase in Bishop score compared to PGE2 gel and pessary.

APPLIED PHYSIOLOGY

- ✓ Uterine cervix contain extra cellular material proteins, Collagen (type I & III), elastin, glycosaminoglycan, especially dermatin sulfate, hyaluronic acid, heparic sulphate, water . Only 10- 15% cervical tissue is composed of smooth muscle.

- ✓ It is well recognized that the cervix loses its firmness in late pregnancy and becomes soft and compliant. During labour it further loses its elasticity , viscosity and plasticity .

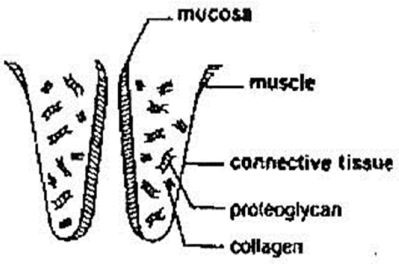
- ✓ Hyaluronic acid contributes to accumulation of water within the substance of cervix, which destabilizes the collagen fibrils, contributing to cervical ripening.

- ✓ Glycosaminoglycans increase and dermatin sulphate decrease at labour . Proteolytic enzymes in cervix degrade cross linked collagen. Collagenase is an enzyme that breaks down collagen. Leucocyte elastase is another enzyme that breaks elastin, proteoglycans.

- ✓ Apart from enzymatic change, cervical remodeling takes place with advancing gestation. Abnormal remodeling of collagen may contribute to dysfunctional labour.

- ✓ Based on current evidence , both prostaglandins and relaxin hormones play a key role in process of cervical ripening. Cervical ripening occur with increase in formation of gap junctions and increase in myometrial contractility.

PHYSIOLOGY OF CERVICAL RIPENING



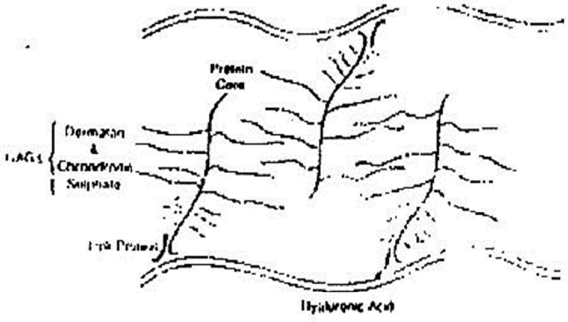
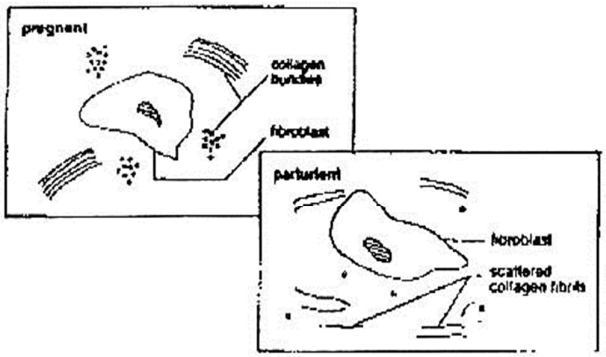
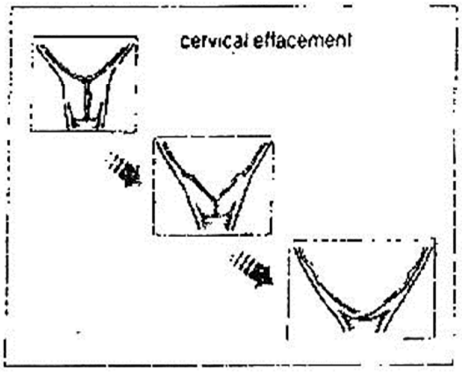


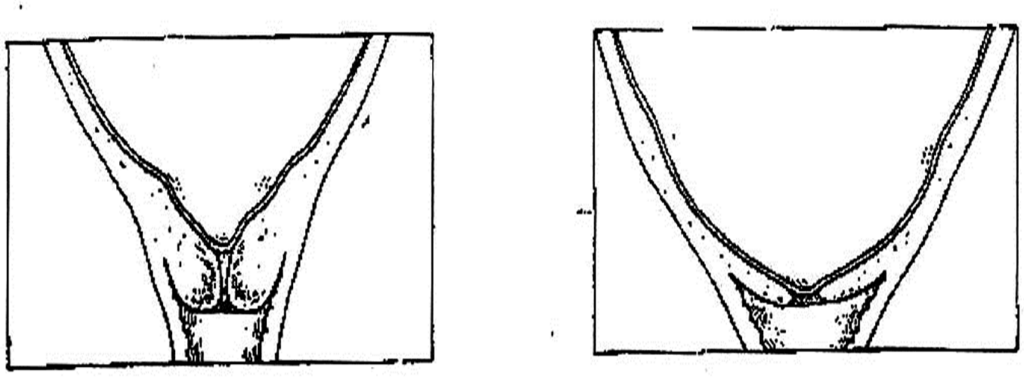
Fig. 3.1 Schematic diagram of proteoglycan complexes including glycosaminoglycans (GAGs) which invest the collagen fibrils in the cervix



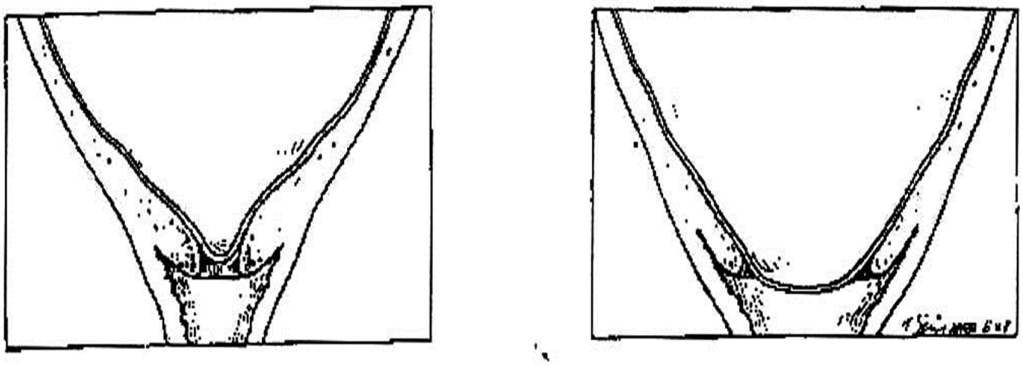


CERVICAL RIPENING

Cervical effacement in primi gravida



Cervical effacement in multi gravida



Methods of cervical ripening

1. NON MEDICAL:

- Sexual intercourse
- Herbal remedies
- Castor oil
- Hot baths
- Breast stimulation
- Acupuncture
- Sweeping of membranes

2. MECHANICAL:

- Foleys catheter
- Extraamniotic saline infusion
- Laminaria tent

3. PHARMACOLOGICAL:

- Oxytocin
- PGS
- Relaxin ,
- Estrogen

4. SURGICAL

ARM

Non- medical methods

- ✓ Sexual intercourse was said to induce labor as the human semen is a source of natural PGS
- ✓ Nipple stimulation does not have any effect in IOL
- ✓ Herbal remedies, castor oil, enema , accupuncture had not been adequately proved.
- ✓ Sweeping of membranes or stripping is an age old method of IOL .

- ➢ Simple technique were a finger is inserted through the cervix and swept around the lower uterine segment above he internal os in a circular motion.
- ➢ It works by the release of PGS .
- ➢ It often stimulates uterine contractions and ripens the cevix

Mechanism of action of EXTRA AMNIOTIC SALINE INFUSION

- ➢ Mechanical action of Foley's catheter is similar to stripping and causes the release of prostaglandins, cytokines in the decidual cells.
- ➢ The lytic enzymes like Phospholipase A , which acts on phospholipids to form Arachidonic acid, which in turn converted to Prostoglandins.
- ➢ Saline infusion cause mechanical stretching of isthmial region thereby production of PGE & F

Mechanism of action of PGE2 GEL

PGE2 gel is available in syringe form that contains 0.5mg of active drug. Local application of PGE2 gel is widely used for cervical ripening.

The intracervical route provides the advantage of introducing uterine activity and cervical dilatation.

Success of induction depends on

- ✓ Period of gestation – uterus is more sensitive near term or post term
- ✓ Gravida – induction is more successful in parous women.
- ✓ Sensitivity of uterus
- ✓ Pre induction scoring – patients with Bishop score >6 respond well to induction than those with unfavorable Bishop score <5

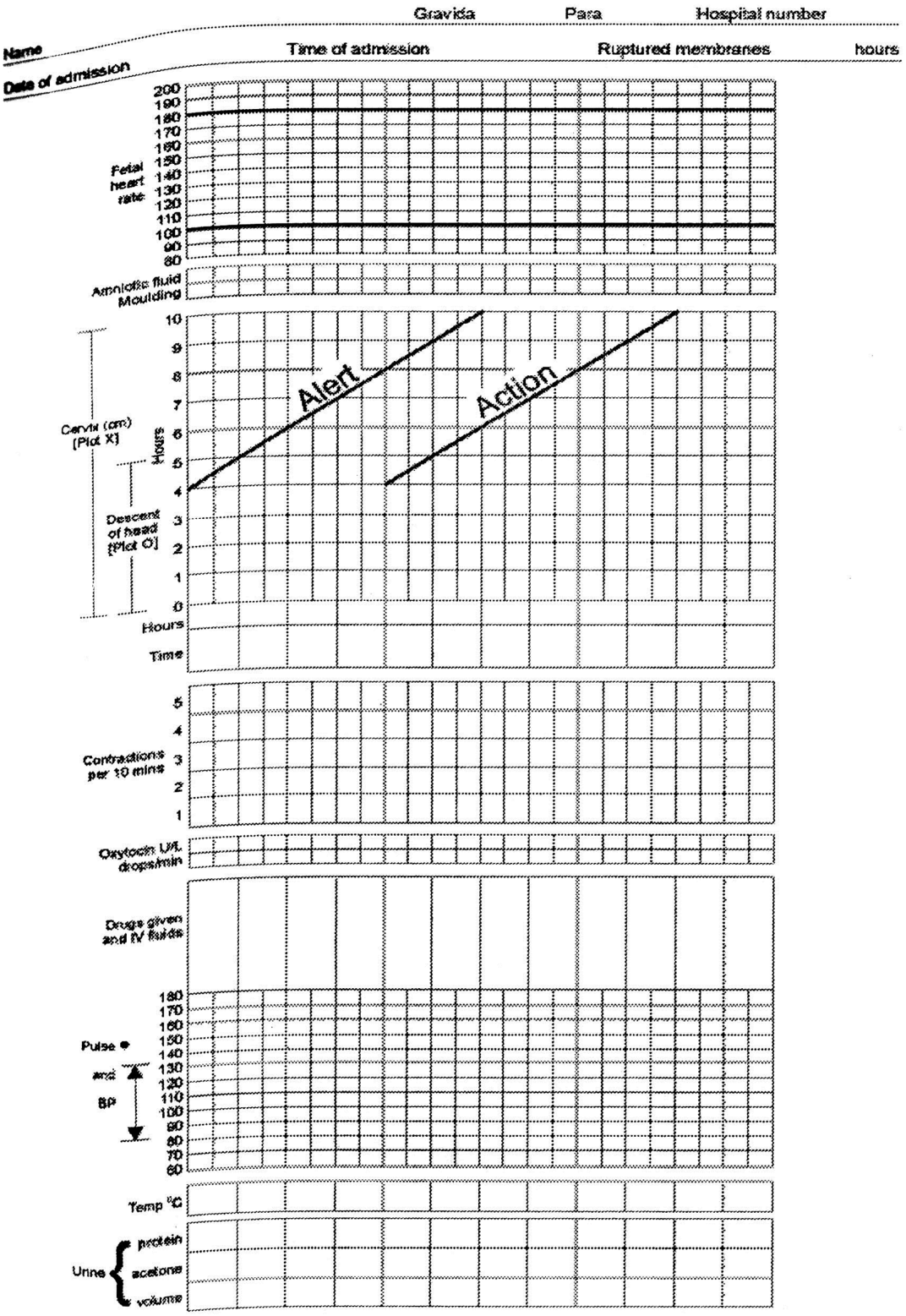
Pre induction scoring

In this study, Bishop scoring system and partogram is used. It is a time – honored fact that Bishop score is a sensitive indicator that predicts successful induction of labour.

BISHOP SCORE

	0	**1**	**2**	**3**
Dilatation	0	1-2	3-4	5-6
Effacement	0-30	40-60	60-70	80+
Station	-3	-2	-1/0	+1/+2
Consistency	Firm	Medium	Soft	
Os position	Posterior	Mid position	Anterior	

PARTOGRAM


Gravida
Para
Hospital number
Name
Time of admission
Ruptured membranes
hours
Date of admission
Fetal heart rate
200
190
180
170
160
150
140
130
120
110
100
90
80
Amniotic fluid
Moulding
Alert
Action
Cervix (cm) [Plot X]
Hours
Descent of head [Plot O]
10
9
8
7
6
5
4
3
2
1
0
Hours
Time
Contractions per 10 mins
5
4
3
2
1
Oxytocin U/L drops/min
Drugs given and IV fluids
Pulse ●
and
BP
180
170
160
150
140
130
120
110
100
90
80
70
60
Temp °C
Urine
protein
acetone
volume

Partogram

It is graphic representation of progress of labour together with information about fetal and maternal condition against time.

The components of partogram are

1. Cervical dilatation in cm
2. Descent of the presenting part
3. Frequency & duration of uterine contractions
4. Fetal heart rate
5. Rupture of membranes and color of amniotic fluid
6. Maternal pulse rate
7. Blood pressure
8. Urine output
9. Drugs used

- An alert line is drawn at the rate of expected progress that is 1cm/hr. An action line is drawn parallel to alert line but 4 hours apart. If labour is abnormal , then cervicograph deviates towards rjght or crosses the action line when definite action is required.
- Partogram is universally accepted method to assess the progress of labour.

AIM OF STUDY

The study is carried out to assess the effectiveness of extra amniotic saline infusion and prostaglandin E2 gel for induction of labour.

OBJECTIVES OF THE STUDY

- ✓ To study the effect of cervical ripening
- ✓ To study the oxytocin augmentation need
- ✓ To see the effect on the labour outcome
- ✓ To study the response difference in primi and multi
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METHODOLOGY

Study centre

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Prospective randomized control study conducted between August 2014 - August 2015

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200 antenatal mothers admitted in the hospital were included in this study.

Inclusion criteria

1. Singleton pregnancy
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3. Absence of infection
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5. Term / Post term pregnancies
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Exclusion criteria

1. Low lying placenta
2. Malpresentation
3. Maternal infection
4. Rupture of membranes
5. Maternal comorbid illnesses like Gestational diabetes, Heart disease, Chronic kidney disease

Induction indications

- Post EDD pregnancies
- oligohydroamnios
- Intra uterine growth restriction
- Gestational hypertension

Before inducing EDD confirmed with regard to LMP, Regularity of menstrual cycles, Early Ultrasonogram scan. Then general examination and obstetric examination carried out.

After ruling out low lying placenta by ultrasonogram, pelvic examination done and Bishop score calculated.

It is a time –honored fact that Bishop Score is a sensitive indicator that predicts successful induction of labour.

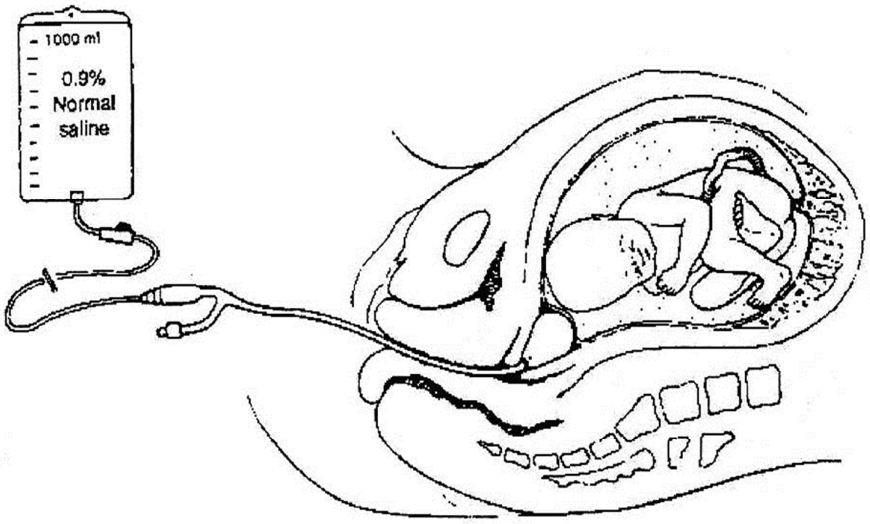
BISHOP SCORE

	0	**1**	**2**	**3**
Dilatation	0	1-2	3-4	5-6
Effacement	0-30	40-60	60-70	80+
Station	-3	-2	-1/0	+1/+2
Consistency	Firm	Medium	Soft	
Os position	Posterior	Mid position	Anterior	

Application

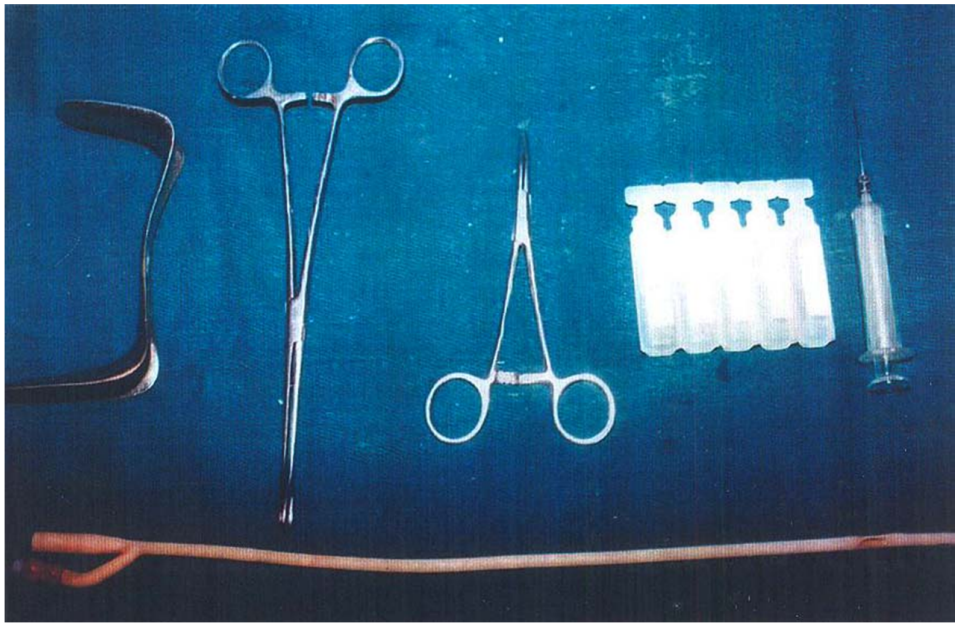
Extra amniotic saline infusion through intra cervical Foley's catheter

- Informed consent from the patient in the labour ward.
- Prophylactic antibiotic injection Ampicillin 1 gm iv given after test dose.
- Patient placed in the lithotomy position.
- Under good light supervision, perineum and vagina cleansed with Betadine solution.
- Under strict asepsis, Foley's catheter NO.16 introduced through the cervix under direct vision.
- Bulb inflated with 40 ml of distilled water and bulb is hitched against the internal os.
- Patient repositioned to left lateral.
- Isotonic saline solution (0.9% Sodium chloride)was instilled through the catheter at the rate of 40ml/hr through infusion pump.
- Patient examined for progress of labour after 6 hours
- If cervical ripening was observed augmentation done by Amniotomy and IV oxytocin or else infusion continued for another 6 hrs.



Balloon dilatation with Extra amniotic saline infusion

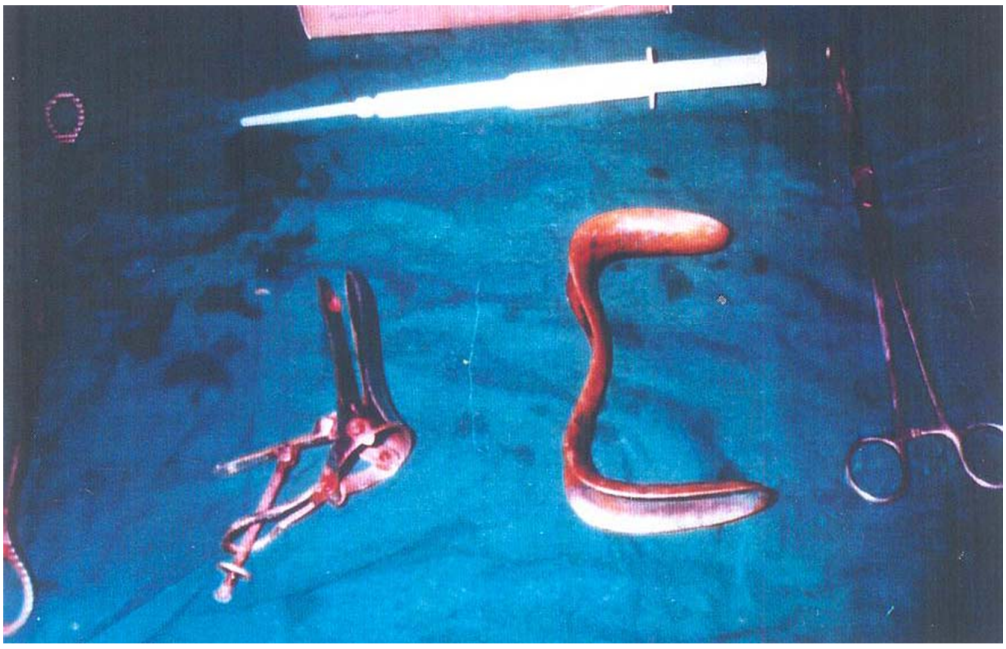
Balloon dilatation with extra amniotic saline infusion



PROSTOGLANDIN E2 GEL instillation

- Informed consent from the patient in the labour ward.
- Prophylactic antibiotic injection Ampicillin 1 gm iv given after test dose.
- Patient placed in the lithotomy position.
- Under good light supervision, perineum and vagina cleansed with Betadine solution.
- Under strict asepsis, cerviprime gel which contains 0.5mg of PGE2 instilled intracervically.
- Patient examined for progress of labour after 6 hours
- If cervical ripening was observed augmentation done by Amniotomy and IV oxytocin or else second dose of gel applied.

PGE2 Gel Instillation



Monitoring parameters

- ✓ Maternal pulse rate, temperature, blood pressure.
- ✓ Uterine contraction for their frequency, duration and strength.
- ✓ Fetal heart rate.
- ✓ Interval between induction and cervical dilatation of 3-4cm was taken as INDUCTION LABOUR INTERVAL (ILI)
- ✓ Interval between induction and delivery of fetus was taken as INDUCTION DELIVERY INTERVAL(IDI)
- ✓ Mother and babies were observed for three days and watched for any puerperal infections and neonatal infections.
- ✓ If there was any evidence of infection, it was treated accordingly.
- ✓ The results were analyzed using t-test and chi- square test.

RESULTS AND ANALYSIS

- The aim of this study was to demonstrate the effectiveness of Extra amniotic saline induction (EASI) & PGE2 gel for cervical ripening and inducing labour.
- 200 mothers selected for the study were analysed using various parameters

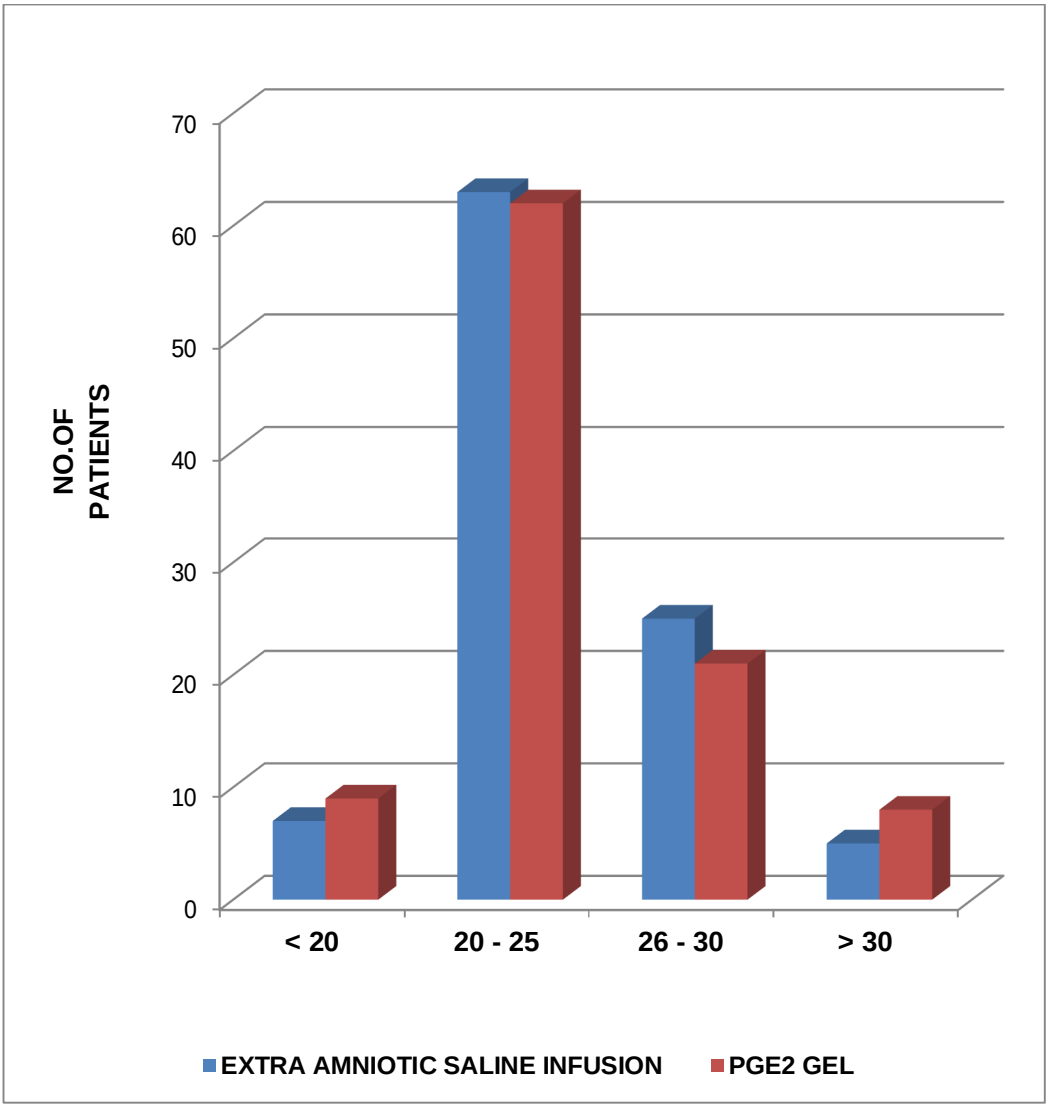
Table -1

DISTRIBUTION OF AGE

AGE IN YEAR	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
<20 yrs	7	7	9	9	16
20-25	63	63	62	62	125
26-30	25	25	21	21	46
>30	5	5	8	8	13
Total	100	100	100	100	200

This table shows the distribution of patients for age in both regimens. Age ranged between 18-33 years in both group of patients. Most of the patients fall between 20-25 years.

Chart 1 : AGE DISTRIBUTIONS FOR TWO GROUPS



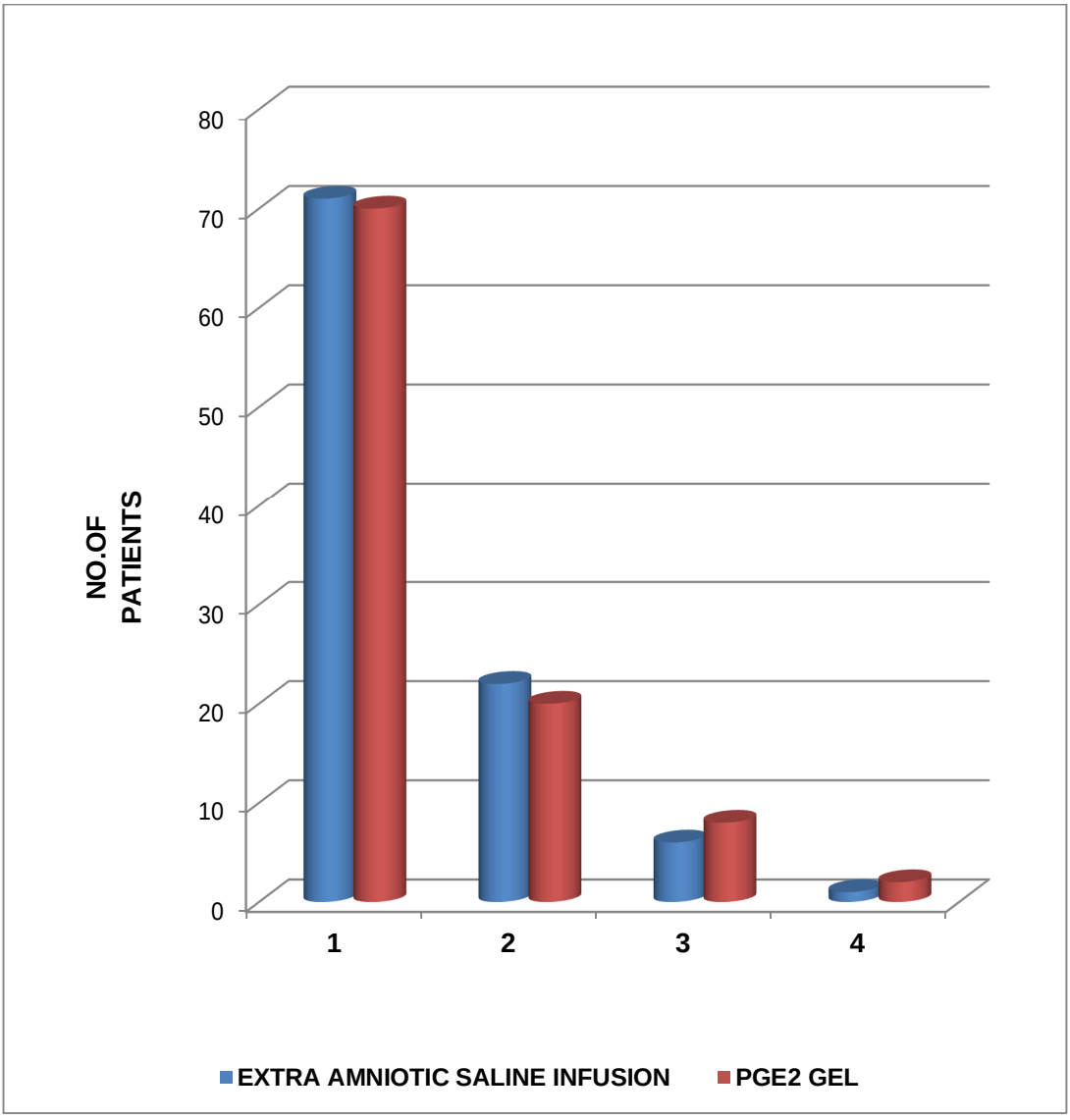
AGE IN YEARS

Table -2 : DISTRIBUTION OF GRAVIDA

GRAVIDA	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
1	71	71	70	70	141
2	22	22	20	20	42
3	6	6	8	8	14
4	1	1	2	2	3
Total	100	100	100	100	200

This shows the distribution of the study group according to gravida.

Chart 2 : GRAVIDA FOR TWO GROUPS



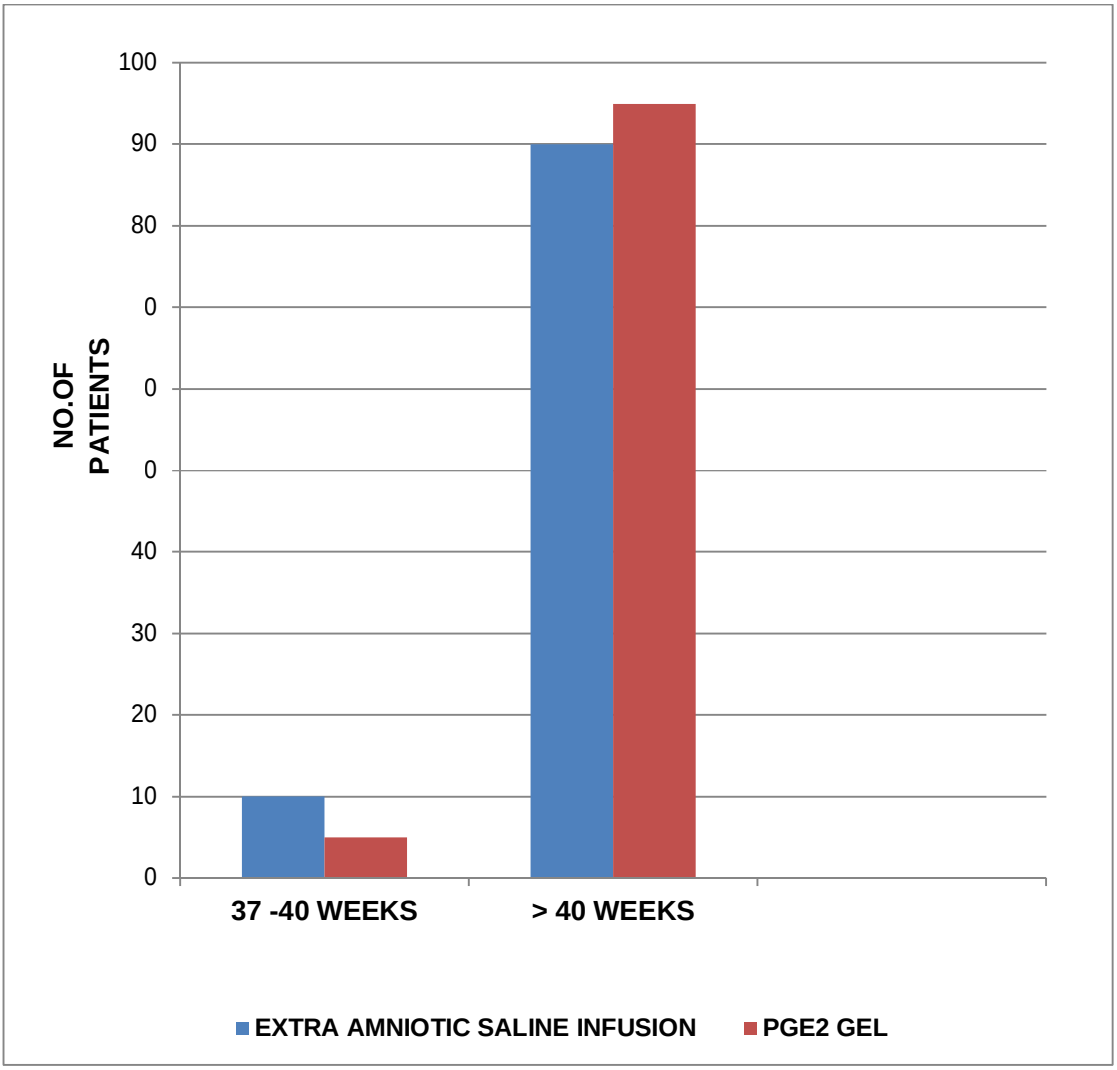
GRAVIDA

Table -3 : DISTRIBUTION OF GESTATIONAL AGE

GESTATION WEEKS	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
37-40	10	10	5	5	15
>40	90	90	95	95	185
Total	100	100	100	100	200

Majority of patients in both the groups had gestational age greater than 40 weeks.

Chart 3 : GESTATIONAL AGE IN WEEKS



UTERUS SIZE

Table -4 : INDICATION FOR INDUCTION

INDICATION	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
POST EDD	86	86	88	88	174
OLIGO	8	8	9	9	17
MILD PIH	6	6	3	3	9
Total	100	100	100	100	200

This shows the distribution of the indication for induction.

Chart -4 : INDICATION IN EASI GROUP

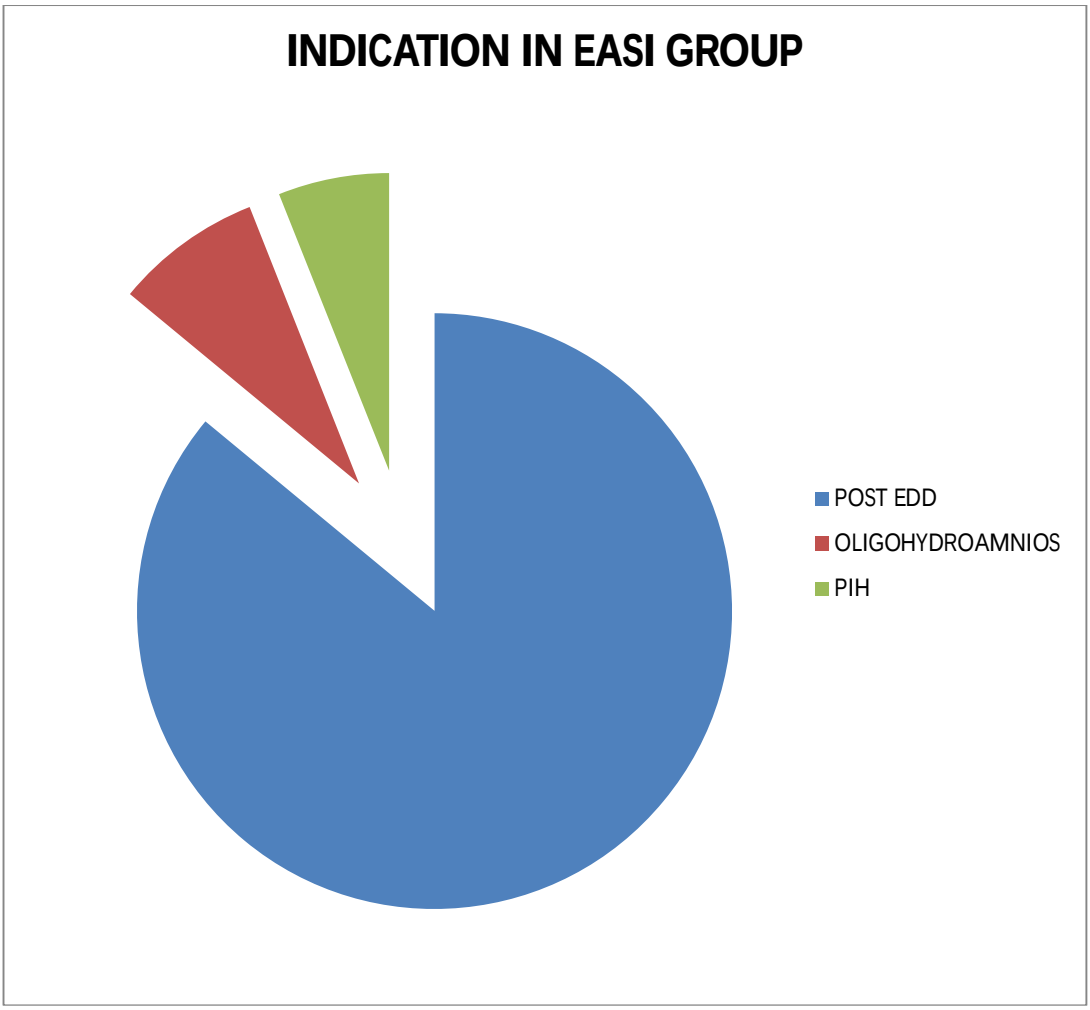


Chart -5 : INDICATION IN EASI GROUP

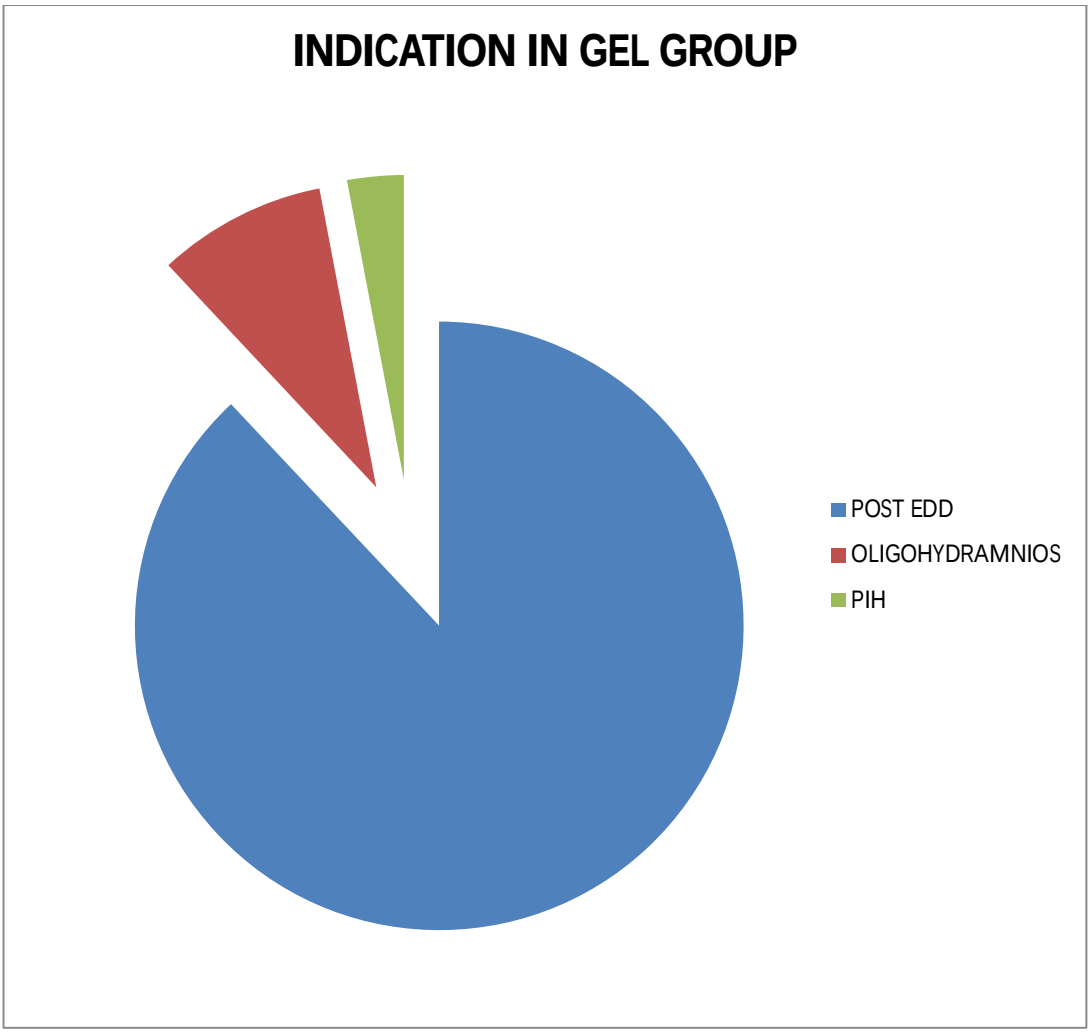
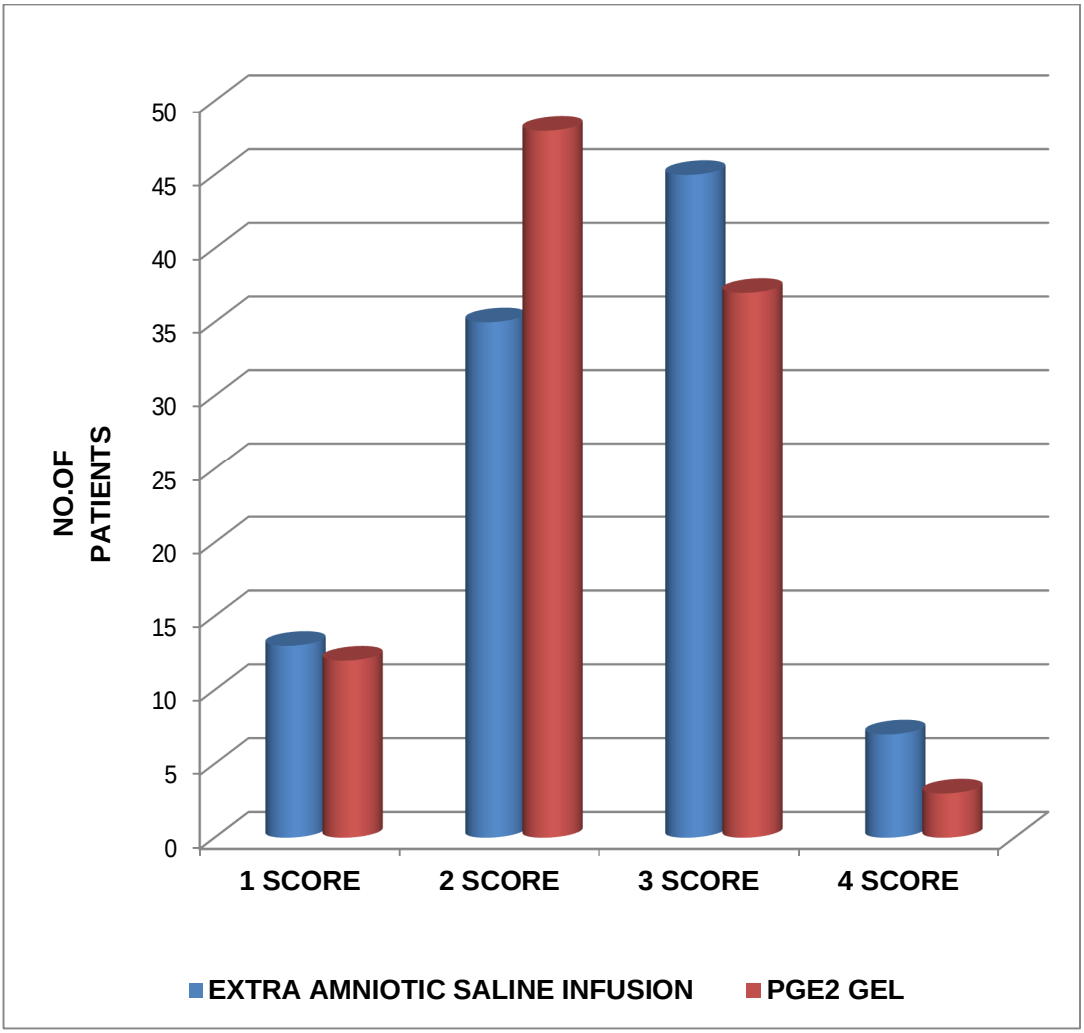


Table -5 : BISHOP SCORE AT ZERO HOUR

BISHOP SCORE	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
0	-	-	-	-	
1	13	13	12	12	25
2	35	35	48	48	83
3	45	45	37	37	82
4	7	7	3	3	10
Total	100	100	100	100	200

This shows the distribution of the distribution of Bishop score at zero hour in both the groups. Bishop score <5 was taken as an indication for induction. Majority of the patients in both groups had bishop score 2 or 3

Chart 6: BISHOP SCORE AT ZERO HOUR



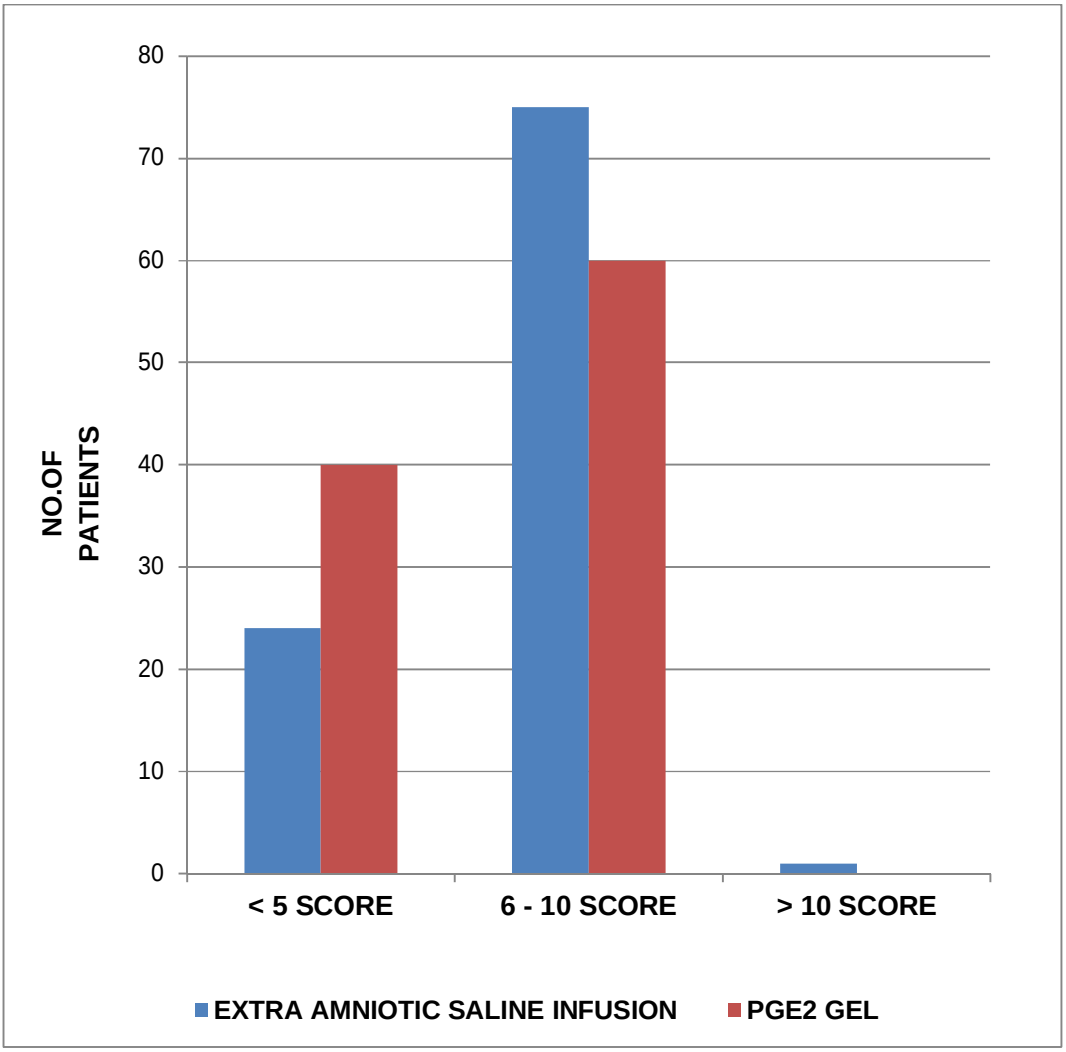
BISHOP SCORE

Table -6 : BISHOP SCORE AT SIX HOUR

BISHOP SCORE	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
<5	24	24	40	40	64
6-10	75	75	60	60	135
>10	1	1	-	-	1
Total	100	100	100	100	200
Mean	7.17		5.93		P<0.01

This table shows the Bishop score at 6 hours in both the groups.75% of patients induced with Extra amniotic saline infusion had favorable Bishop score within 6 hours. Only 60% of patients induced with PGE2 gel had favorable Bishop score within 6 hours.

Chart 7 : BISHOP SCORE AT SIX HOUR



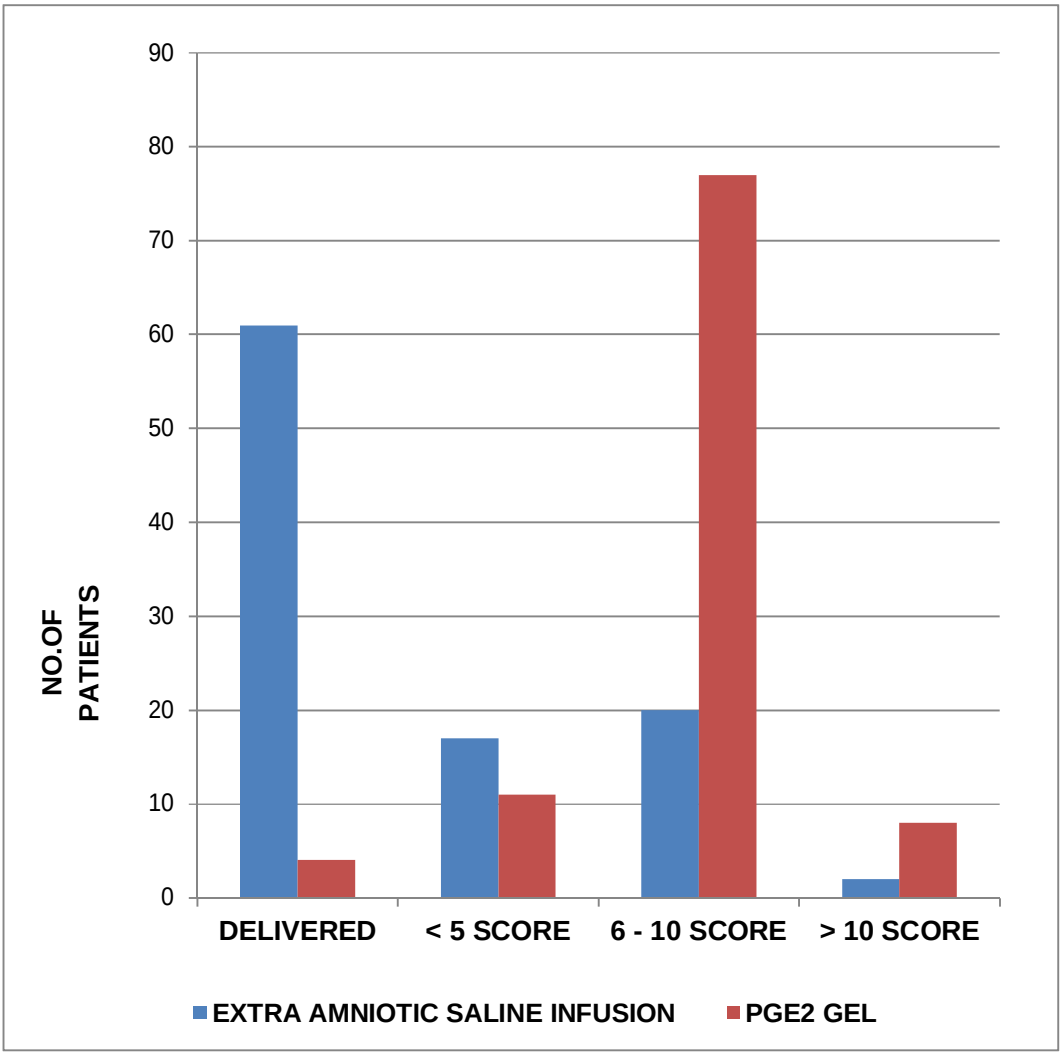
BISHOP SCORE

Table -7 : BISHOP SCORE AT TWELVE HOUR

BISHOP SCORE	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
Delivered	61	61	4	4	65
>10	17	17	11	11	28
6-10	20	20	77	77	97
<5	2	2	8	8	10
Total	100	100	100	100	200
Mean	9.37		8.44		P<0.01

60% of patients in the Balloon dilatation with Extra amniotic saline infusion delivered within 12 hours. Only 4% of patients in the PGE2 gel delivered within 12 hours.

Chart 8 : BISHOP SCORE AT 12 HOUR



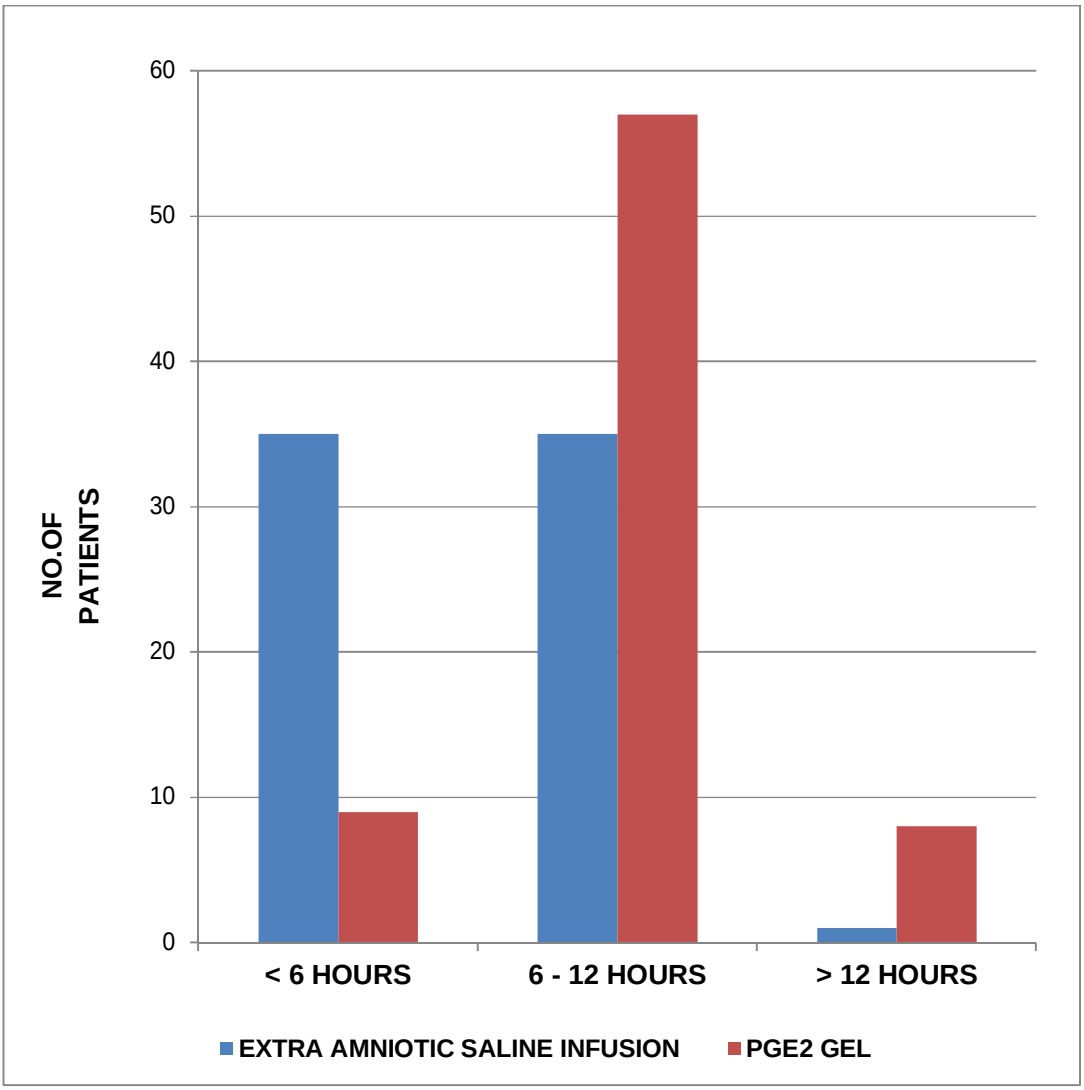
BISHOP SCORE

Table -8 : INDUCTION TO ACTIVE LABOUR INTERVAL

DURATION IN HOURS	EXTRA AMNIOTIC SALINE INFUSION				PGE2 GEL			
	PRIMI		MULTI		PRIMI		MULTI	
	NO.	%	NO.	%	NO.	%	NO.	%
<6	35	49.2	21	73.8	9	13.3	10	33.3
6-12	35	49.2	8	26.2	57	80.9	20	66.7
>12	1	1.6	-	-	4	5.8	-	-
Total	71	100	29	100	70	100	30	100

The above table shows the induction to active labour interval. Most of the patients in the Extra amniotic saline infusion group established active labour within 6 hours. Whereas most of the patients in the PGE2 gel group established active labour between 6- 12hrs.

Chart 9 : DISTRIBUTION OF INDUCTION LABOUR INTERVAL FOR PRIMI GRAVIDA



TIME IN HOURS

Chart 10 : DISTRIBUTION OF INDUCTION LABOUR INTERVAL FOR MULTI GRAVIDA

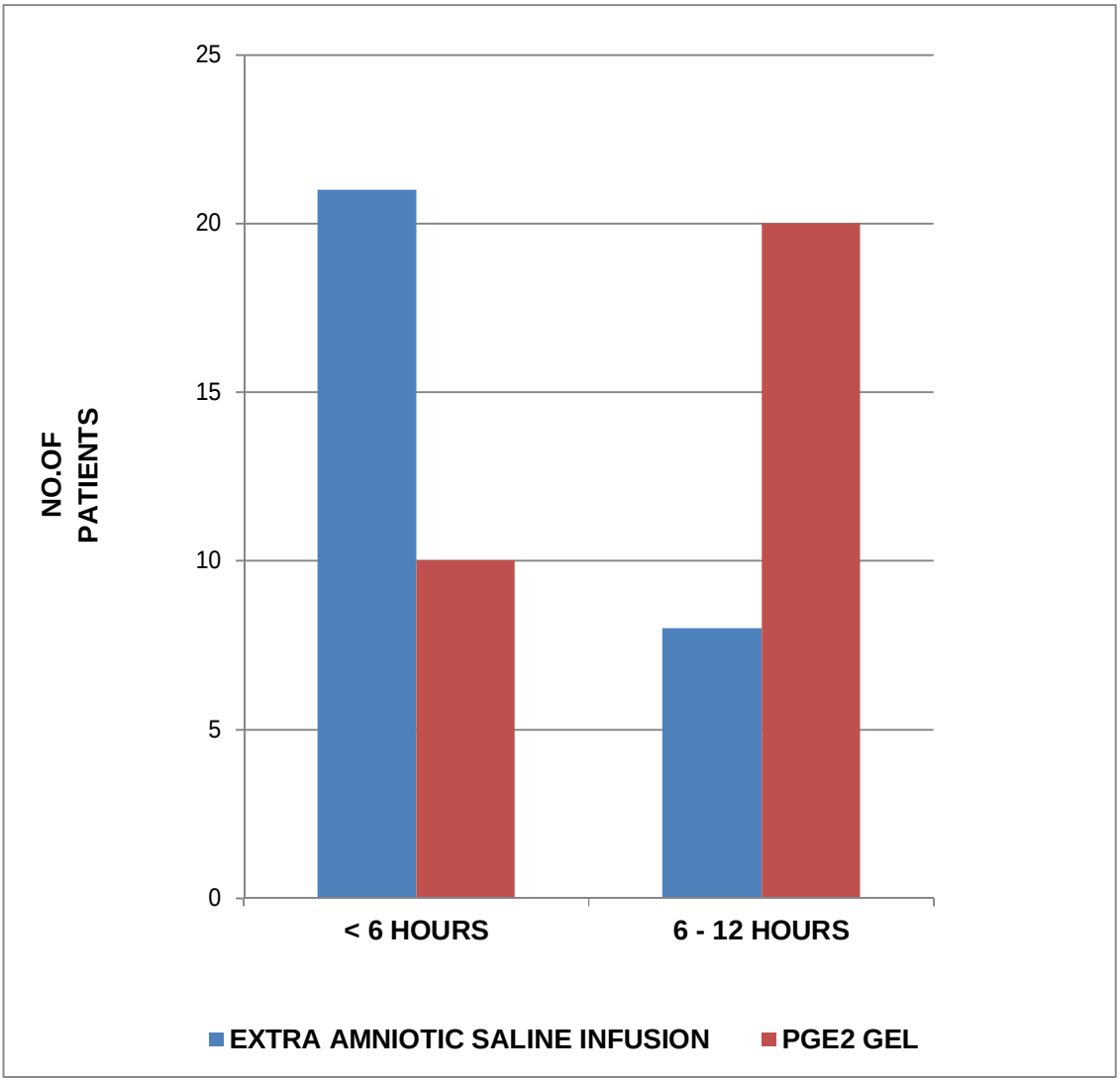


Table -9 : MEAN INDUCTION TO ACTIVE LABOUR INTERVAL

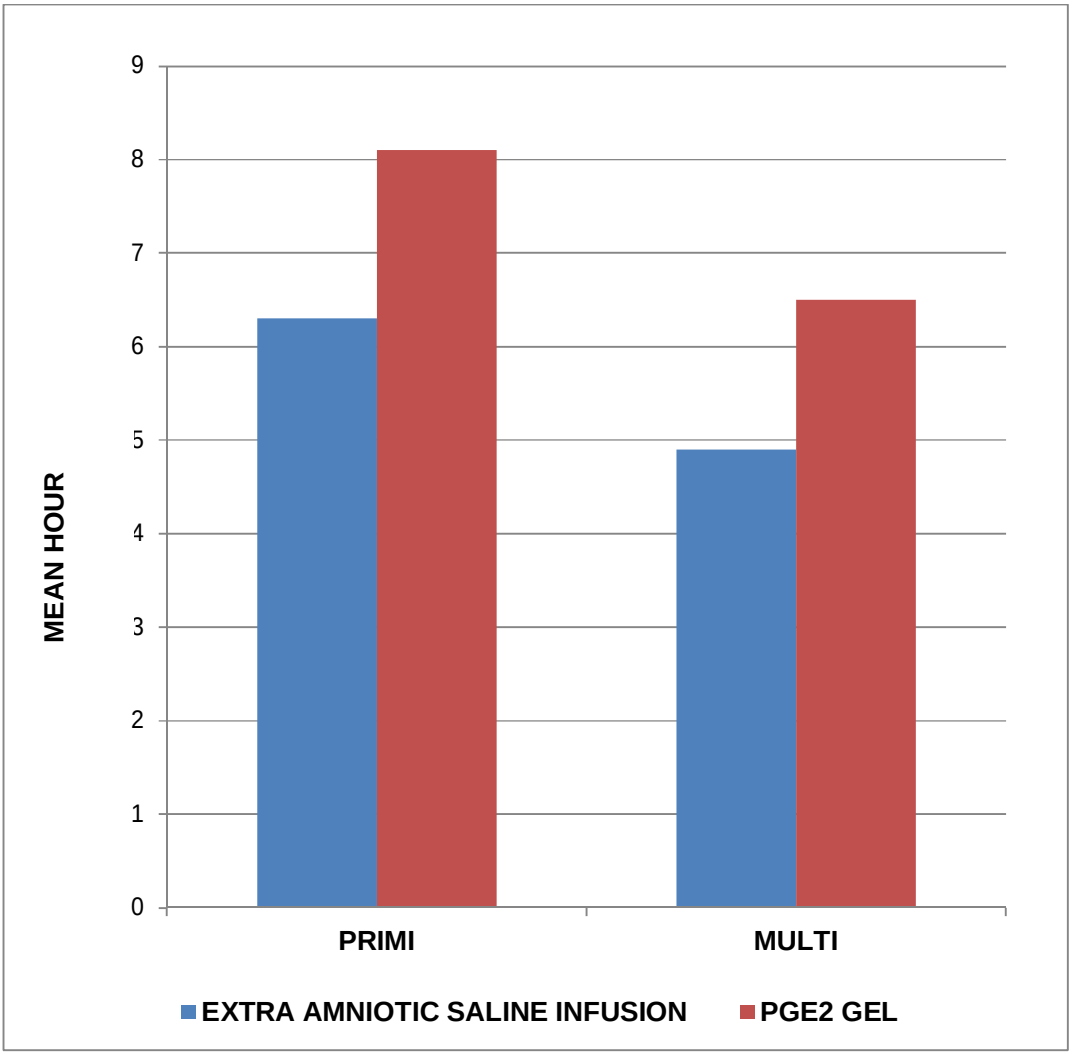
	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL	
	PRIMI	**MULTI**	**PRIMI**	**MULTI**
IDL	6.35+2.12	4.98+0.96	8.03+2.18	6.55+1.37

The mean Induction active labour interval in primi with Extra amniotic saline infusion was 6.35hrs. The mean Induction to active labour interval in primi with PGE2 gel was 8.03hrs.

The mean Induction active labour interval in multiparous with Extra amniotic saline jnfusion was 4.98hrs. The mean Induction to active labour interval in multiparous with PGE2 gel was 6.55hrs.

The difference between the two groups is statistically significant.

Chart 11 : MEAN HOUR OF INDUCTION LABOUR INTERVAL



GRAVIDA

Table -10 : INDUCTION DELIVERY INTERVAL

DURATION IN HOURS	EXTRA AMNIOTIC SALINE INFUSION				PGE2 GEL			
	PRIMI		MULTI		PRIMI		MULTI	
	NO.	%	NO.	%	NO.	%	NO.	%
6-12	44	62.0	28	97.6	31	44.8	17	55.6
12-24	27	38.0	1	2.4	39	55.2	13	44.4
Total	71	100	29	100	70	100	30	100

62% of Primi delivered within 12 hrs in the Extra amniotic saline infusion group compared to only 44.8% in the PGE2 gel group. 97.6% of Multi delivered within 12 hrs in Extra amniotic saline infusion group compared to only 55.6% in the PGE2 gel group.

Chart 12 : DISTRIBUTION OF INDUCTION DELIVERY INTERVAL FOR PRIMI GRAVIDA

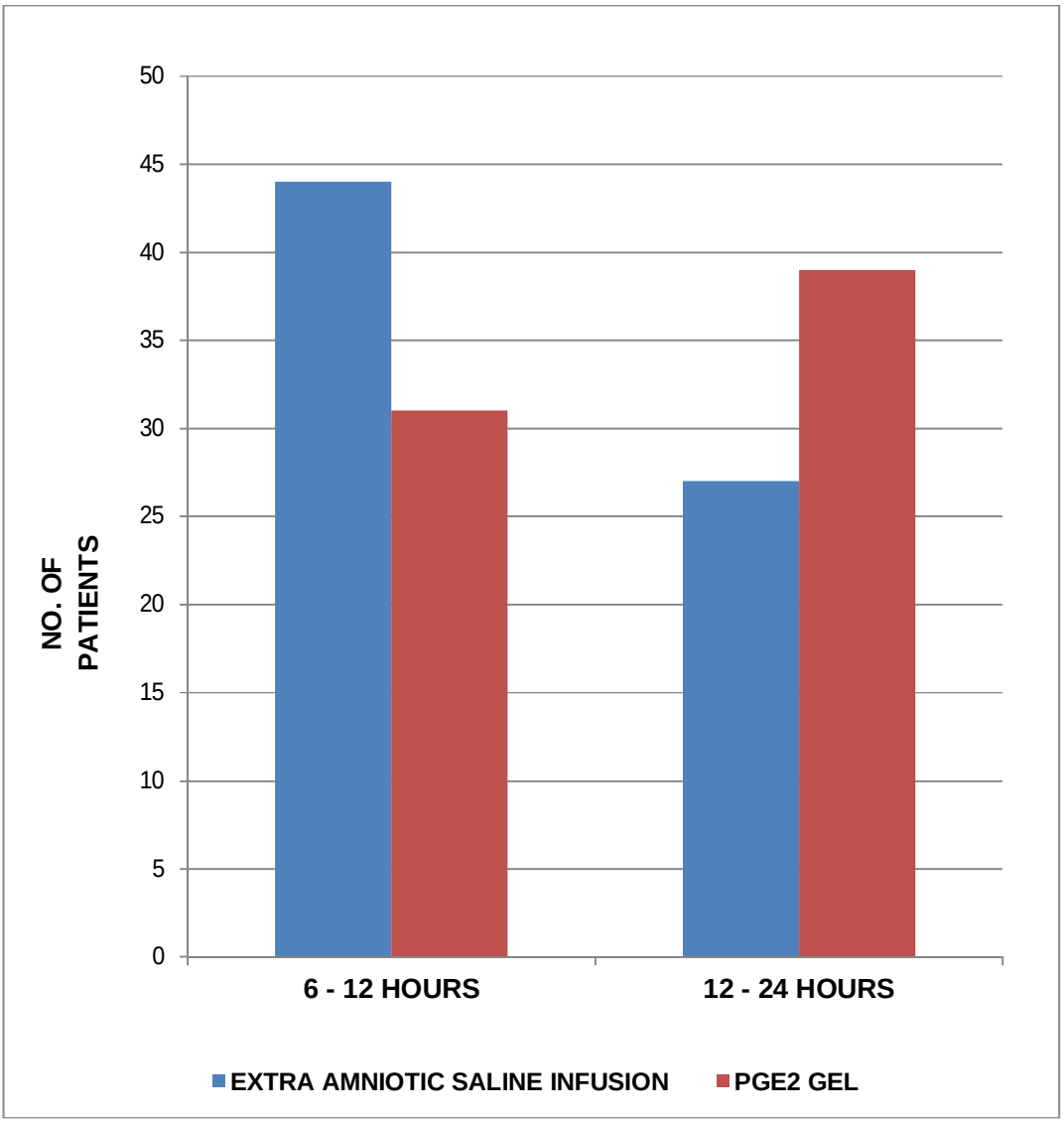
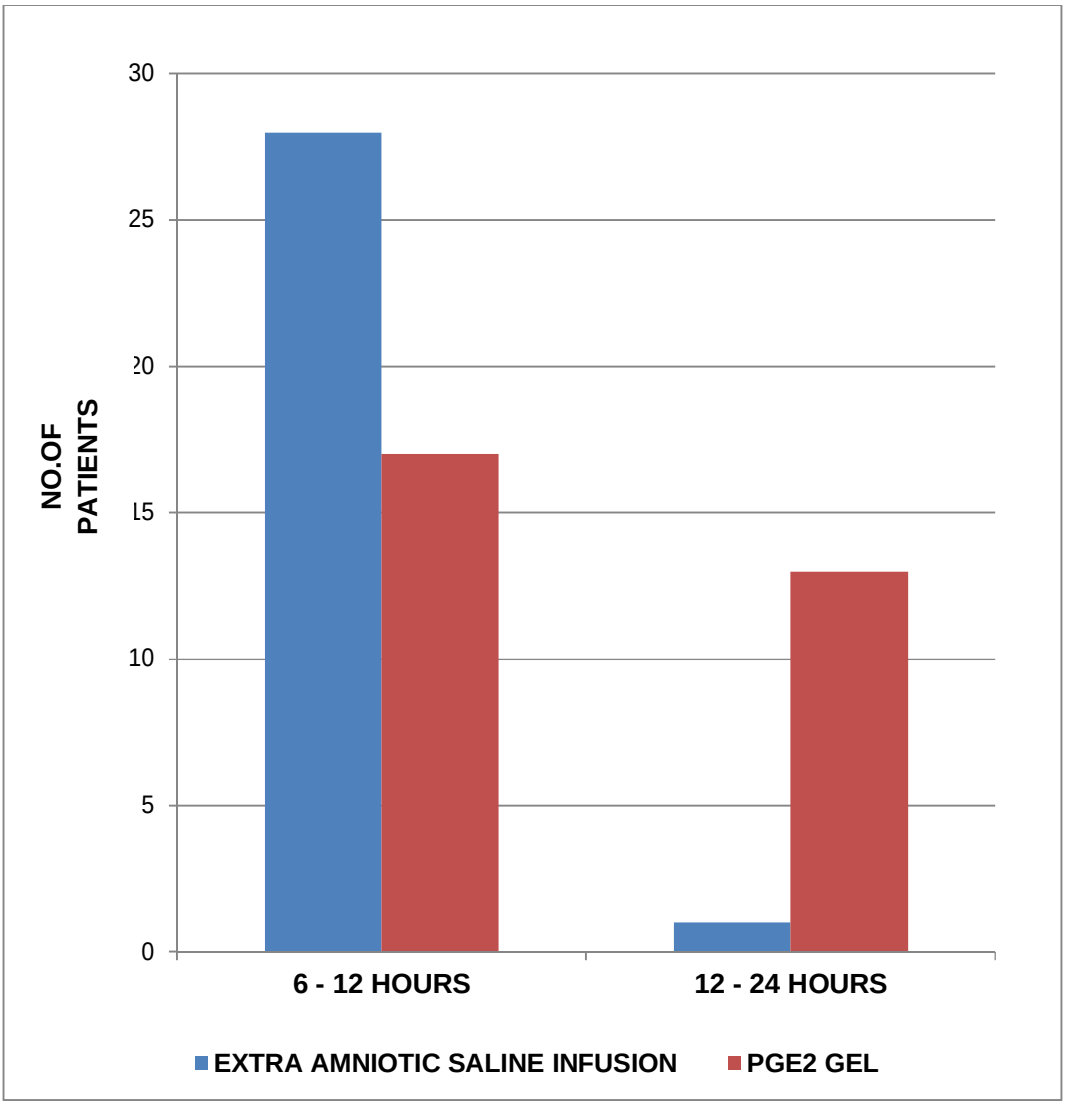


Chart 13 : DISTRIBUTION OF INDUCTION DELIVERY INTERVAL FOR MULTI GRAVIDA



TIME IN HOURS

Table -11 : MEAN INDUCTION DELIVERY INTERVAL

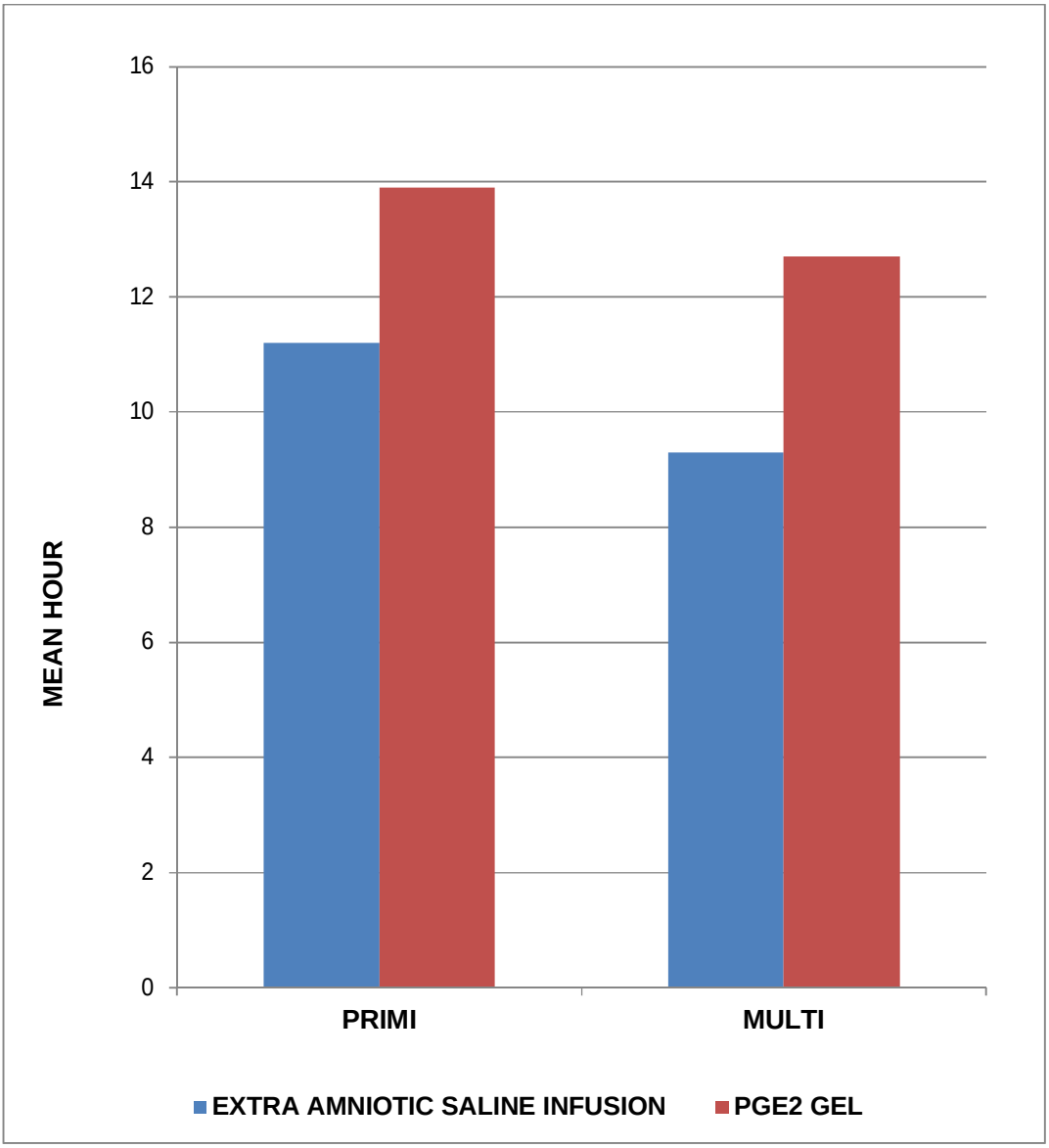
	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL	
	PRIMI	**MULTI**	**PRIMI**	**MULTI**
IDL	11.21+2.72	9.30+1.71	13.94+3.32	12.78+2.38

The mean Induction delivery interval in Primi with Extra amniotic saline infusion was 11.2 hrs. The mean Induction to delivery interval in Primi with PGE2 gel was 13.94 hrs.

The mean Induction to delivery interval in Multi with Extra amniotic saline infusion was 9.30hrs. The mean Inductio to delivery interval in Multi with PGE2 gel was 12.78 hrs.

The difference between the two group is statistically significant.

Chart 14 : MEAN HOUR OF INDUCTION DELIVERY INTERVAL



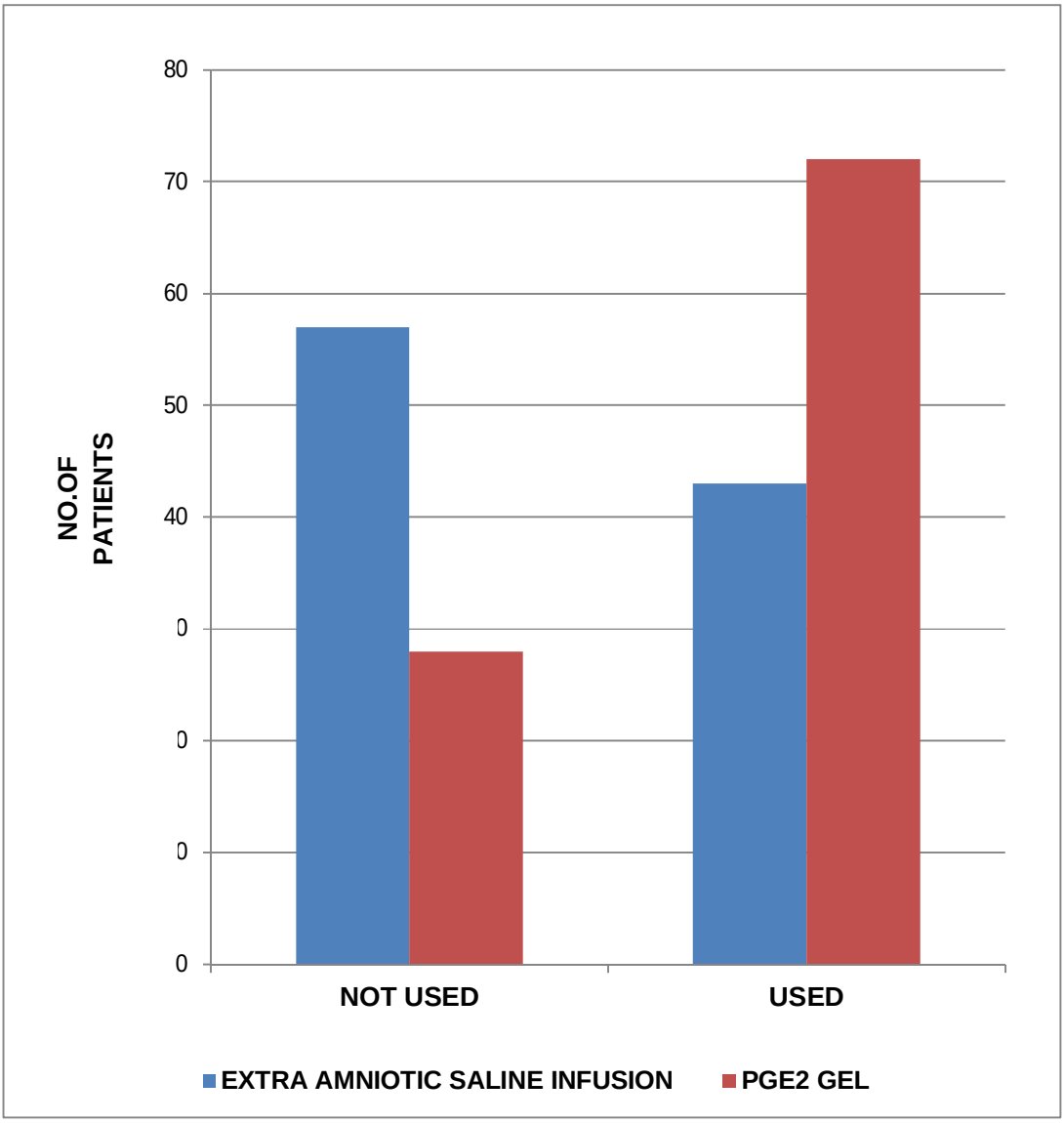
GRAVIDA

Table -12 : PATIENTS REQUIRING OXYTOCIN AUGMENTATION

OXYTOCIN	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
NOT USED	57	57	28	28	85
USED	43	43	72	72	115
Total	100	100	100	100	200

This table shows the higher use of Oxytocin in the PGE2 gel group – 73% when compared to Extra amniotic saline infusion group – 43%. The difference is statistically significant.

Chart 15 : USAGE OF OXYTOCIN



OXYTOCIN

Table -13 : MODE OF DELIVERY DISTRIBUTION

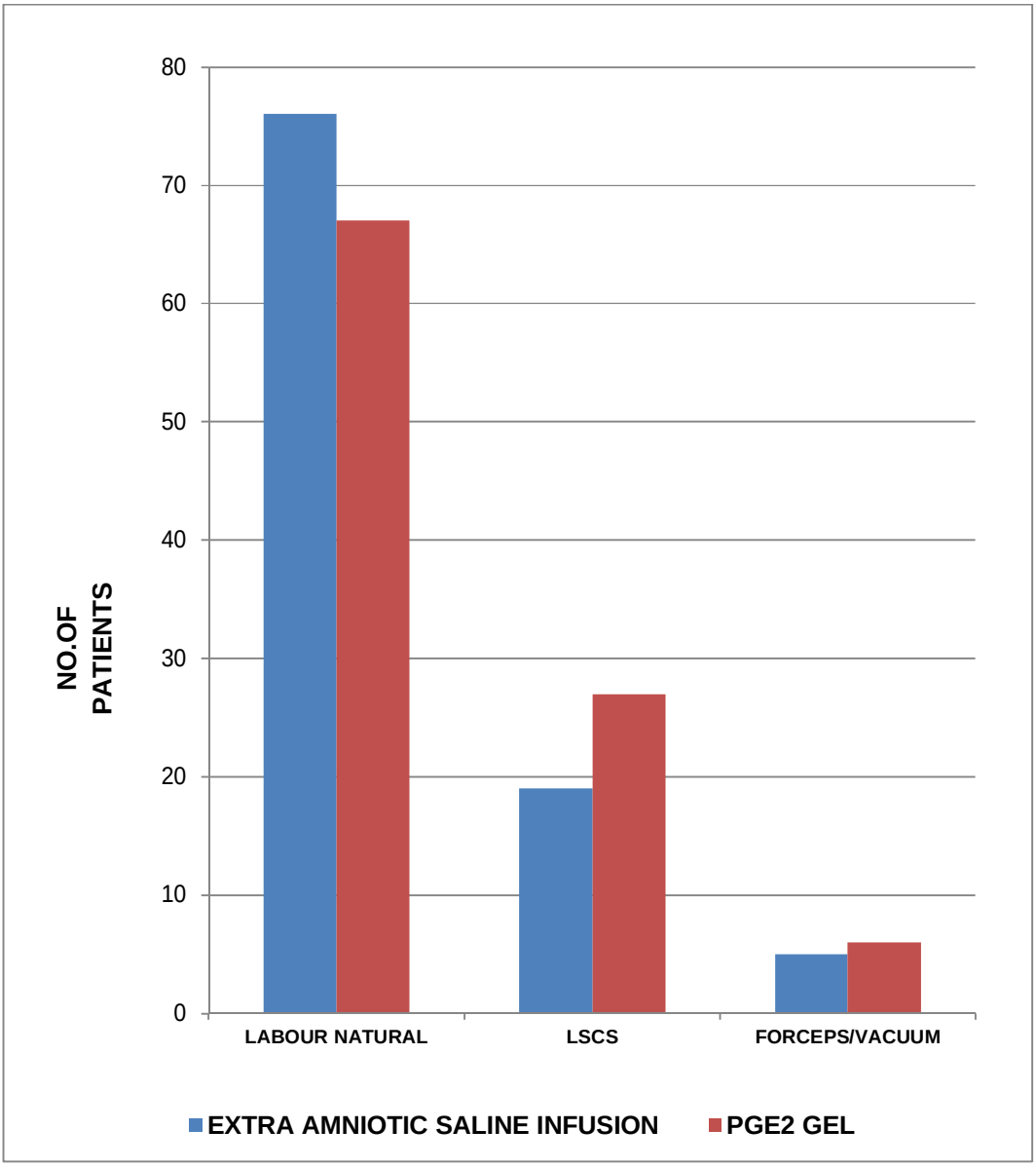
MODE OF DELIVERY	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
LABOUR NATURAL	76	76	67	67	143
LSCS	19	19	27	27	46
FORCEPS/ VACUUM	5	5	6	6	11
Total	100	100	100	100	200

76% of patients in Extra amniotic saline infusion delivered vaginally compared to only 67% in the PGE2 gel.

LSCS was 27% in the PGE2 gel group whereas it was only 19% in the Extra amniotic saline infusion.

The difference is statistically significant.

Chart 16 : MODE OF DELIVERY DISTRIBUTION



MODE OF DELIVERY

Table -14 : INDICATION FOR CESAREAN SECTION

INDICATION	EXTRA AMNIOTIC SALINE INFUSION	PGE2 GEL	TOTAL
	NUMBER	NUMBER	
FETAL DISTRESS	12	19	31
CPD	3	1	4
FAILED INDUCTION	3	6	9
OTHERS	1	1	2
Total	19	27	46

Incidence of Cesarean section was lower in Extra amniotic saline infusion group compared to PGE2 gel group. Failed induction in Extra amniotic saline infusion group was only 3% compared to 6% in PGE2 gel group. The difference is statistically significant.

Chart 17 : INDICATION FOR LSCS IN EXTRA

AMNIOTIC SALINE INFUSION

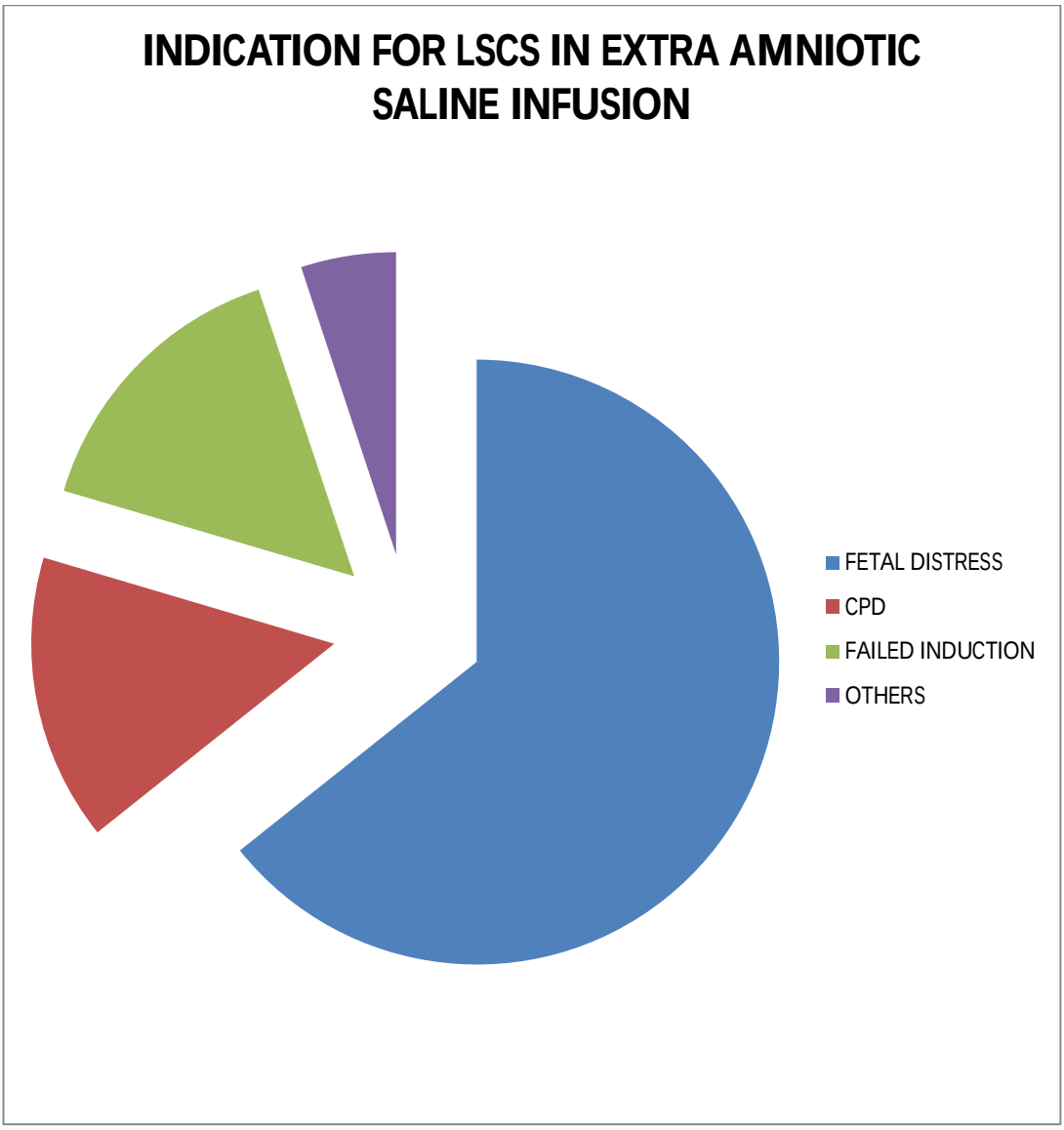


Chart 18 : INDICATION FOR LSCS IN PGE2 GEL

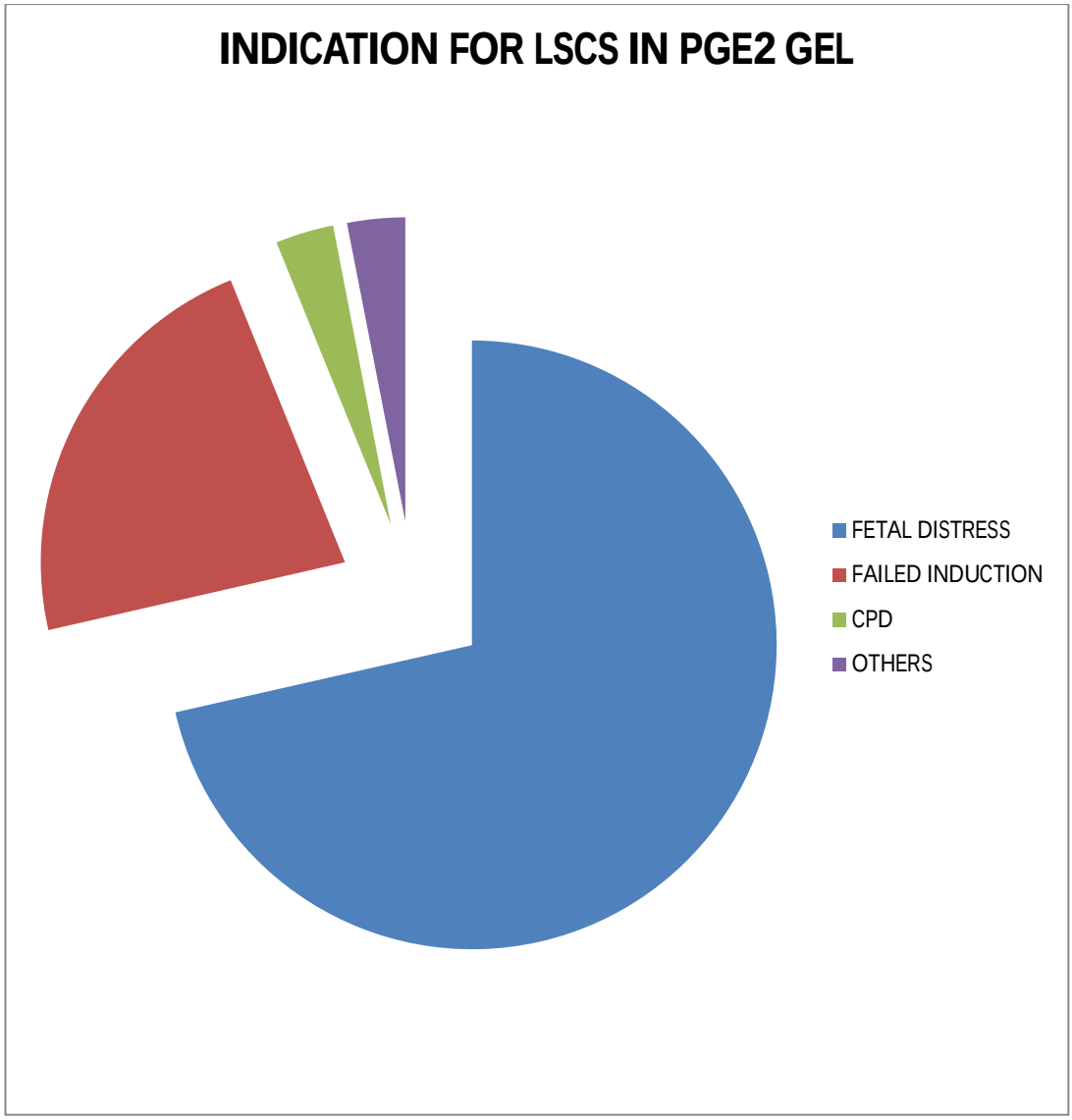


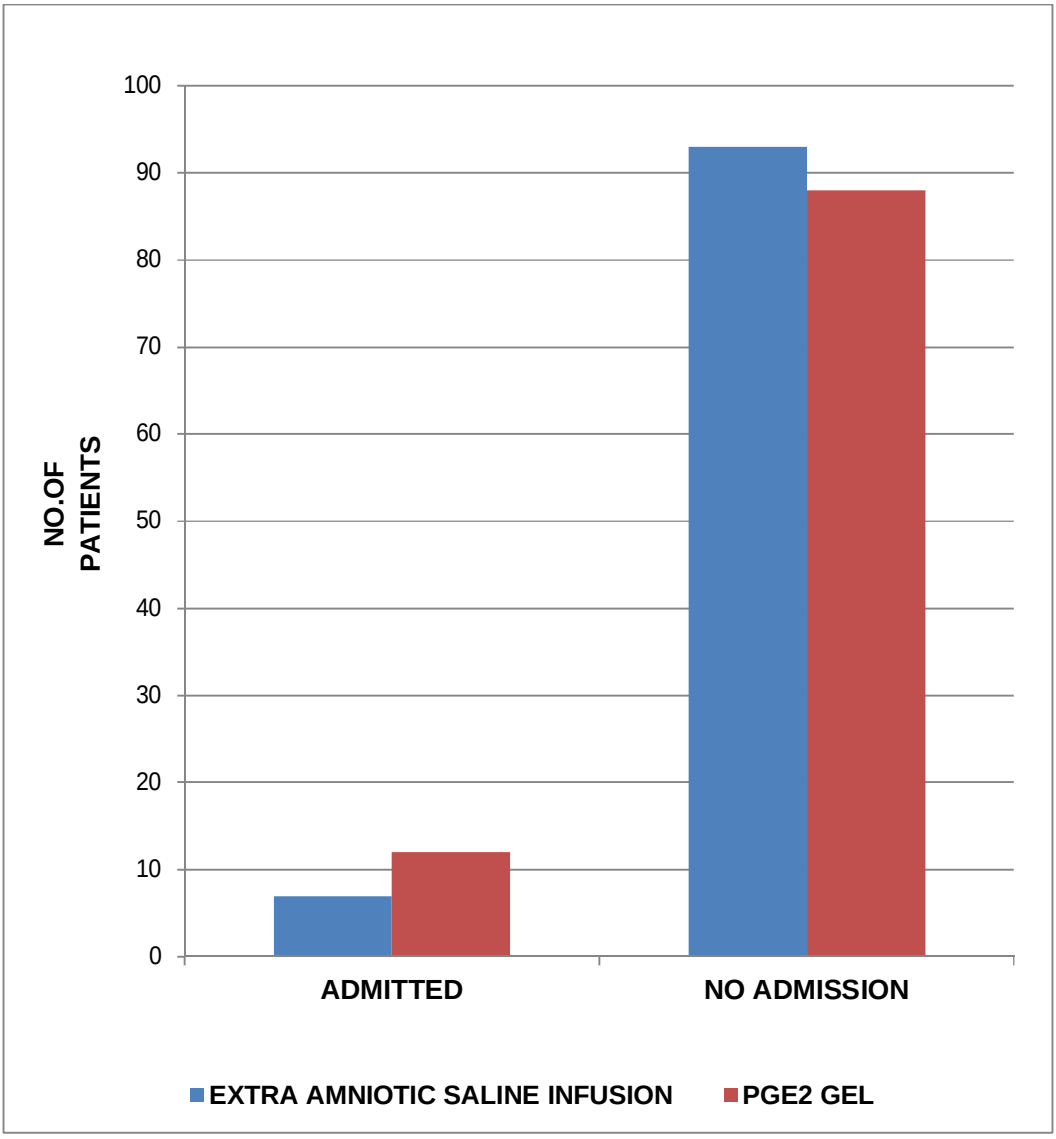
Table -15 : FETAL OUTCOME

ADMISSION IN NICU	EXTRA AMNIOTIC SALINE INFUSION		PGE2 GEL		TOTAL
	NUMBER	PERCENT	NUMBER	PERCENT	
YES	7	7	12	12	19
NO	93	93	88	88	181
Total	100	100	100	100	200

Only 7% neonates were admitted in NICU in the Extra amniotic saline infusion group compared to 12% admissions in PGE2 gel.

The cause for admission was Birth asphyxia, meconium aspiration.

Chart 19 : NEONATAL OUTCOME



NICU ADMISSION

Table -15 : MATERNAL OUTCOME

	EXTRA AMNIOTIC SALINE INFUSION	**PGE2 GEL**
	NUMBER	**NUMBER**
HYPER STIMULATION	-	6
POST PARTUM HEMORRHAGE	5	11
PUPERAL PYREXIA	7	5
TOTAL	12	22

No hyperstimulation was noted in Extra amniotic saline infusion whereas 6 had hyperstimulation in PGE2 gel group. PPH was also more in PGE2 gel. Puperal pyrexia was comparable in both the groups.

Chart 20 : MATERNAL HYPERSTIMULATION

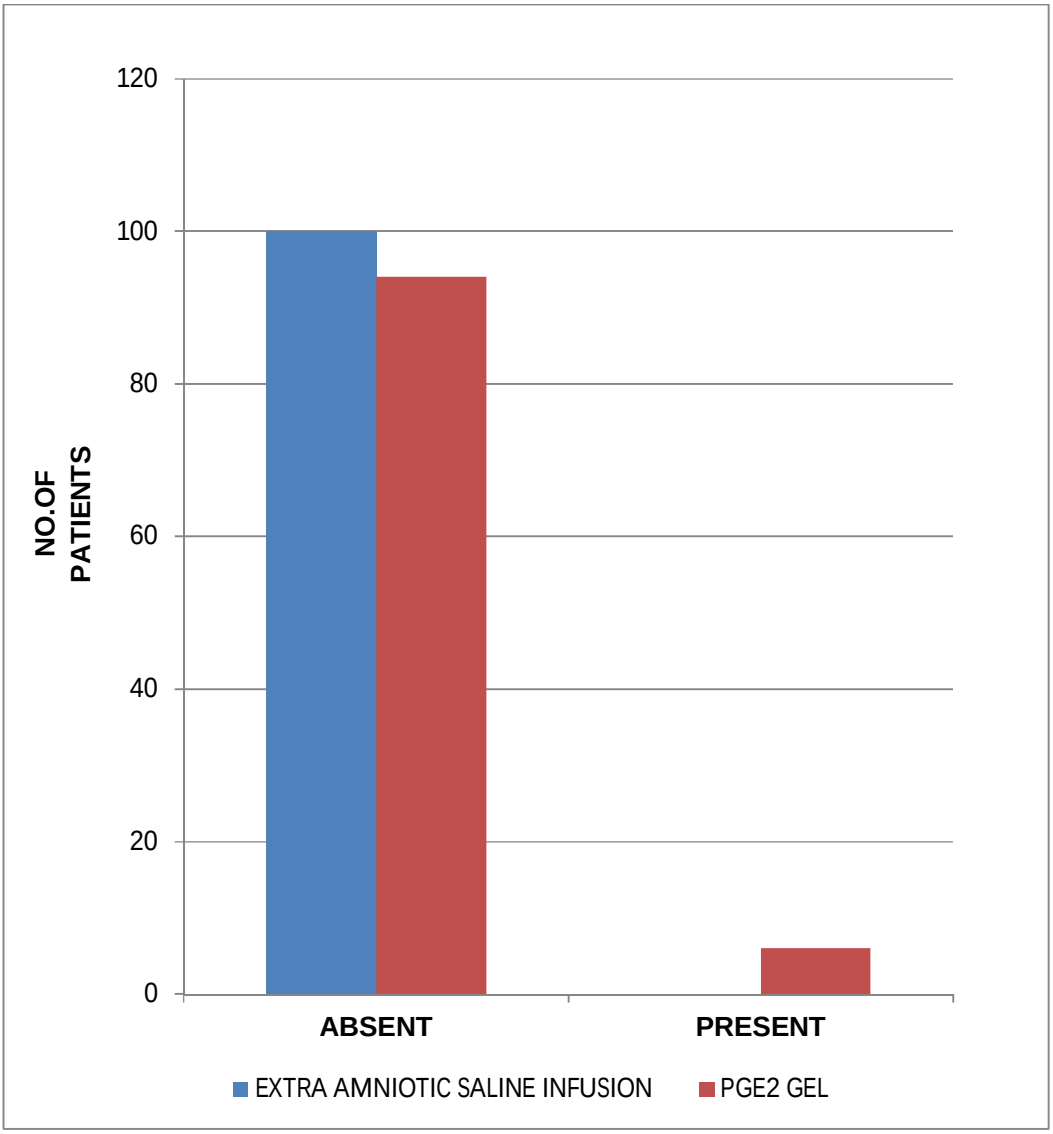


Chart 21 : POST PARTUM HEMORRHAGE

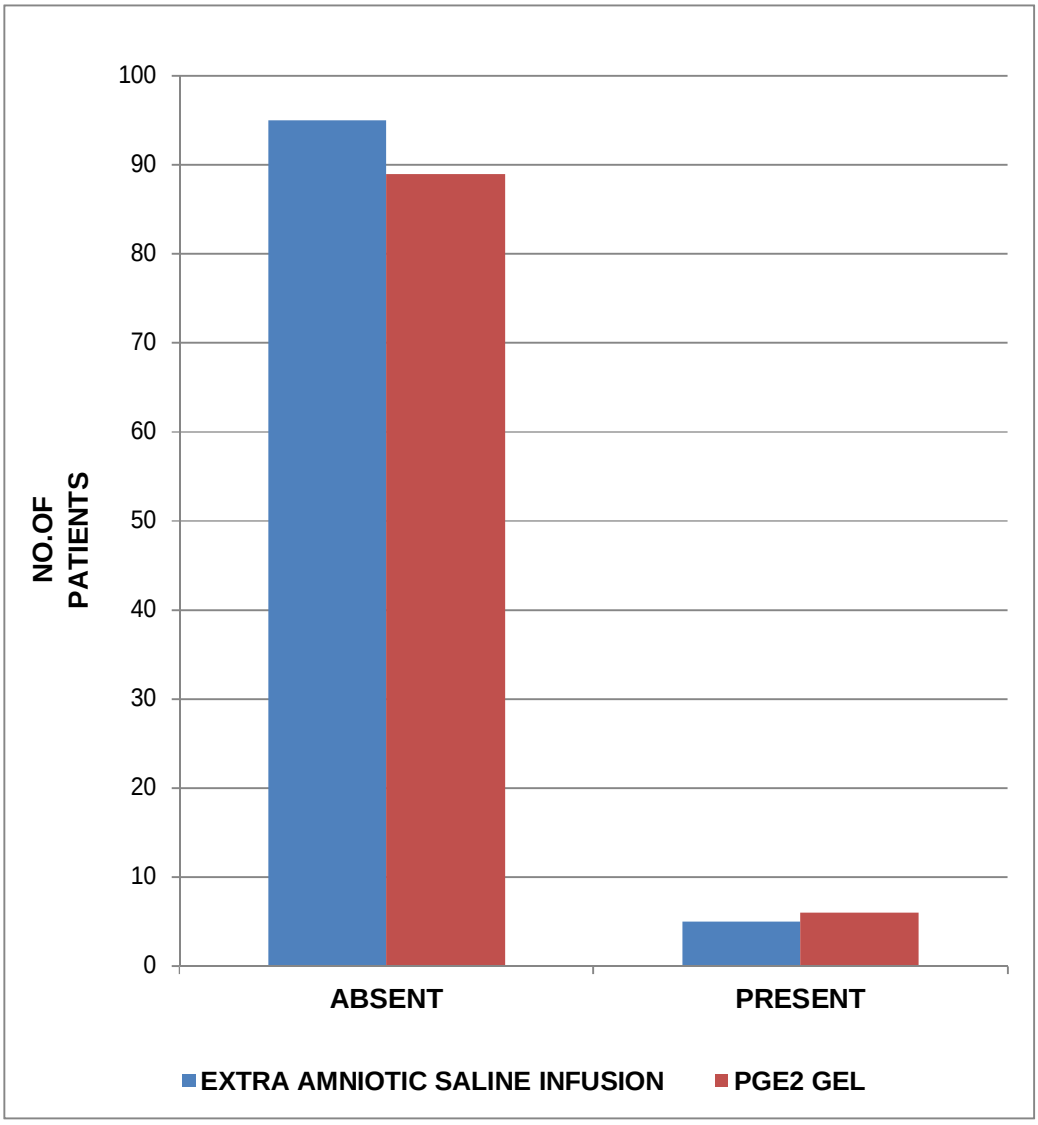
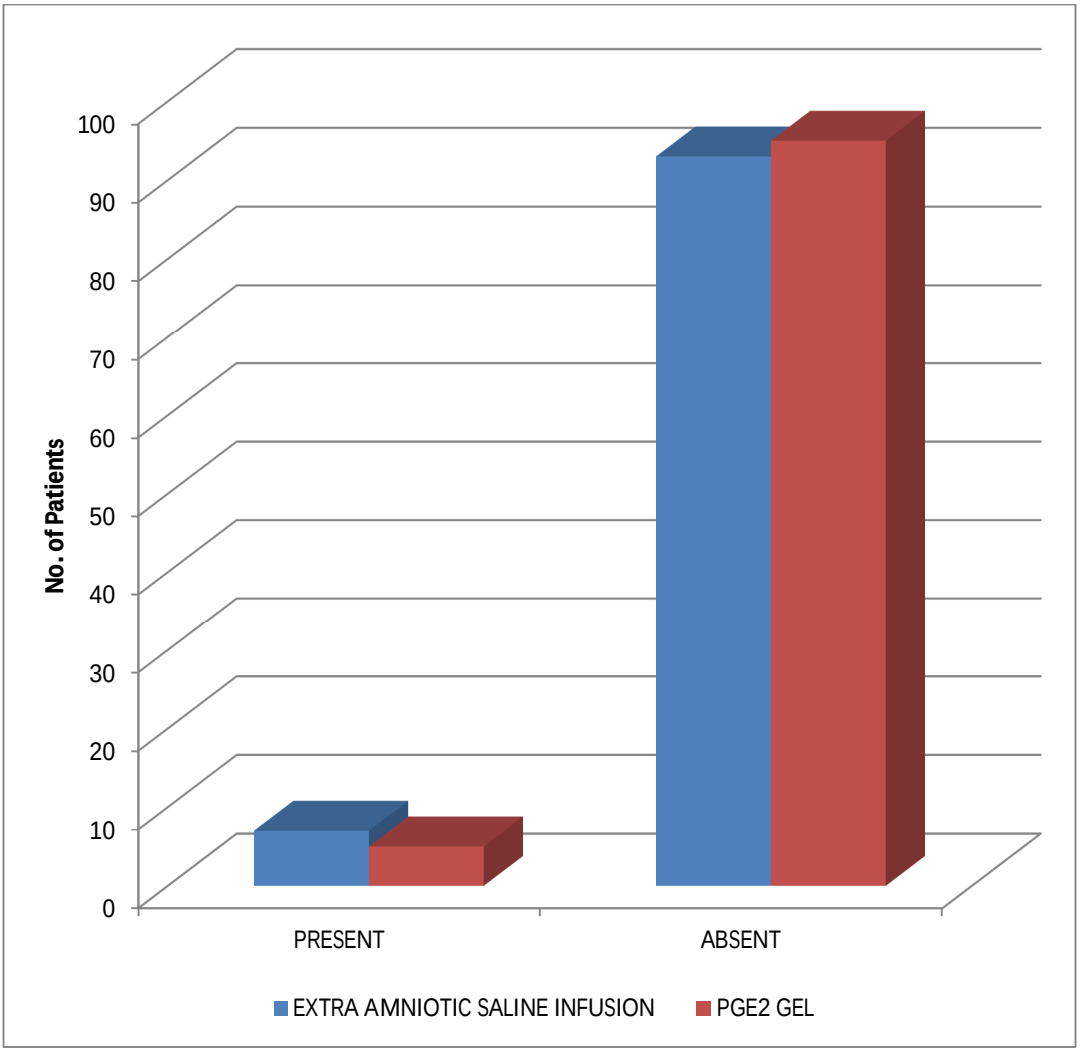


Chart 22: PUPERAL PYREXIA



DISCUSSION

- The study was conducted in Institute of Obstetrics andGynecology, Egmore to compare the efficacy of Extra amniotic saline infusion and PGE2 gel for induction of labour.

- The study was carried out in 200 patients. 100 patients were induced with Extra amniotic saline infusion and 100 patients were induced with PGE2 gel.

- Both the groups had patients of almost similar age, parity and gestational age.

- Majority of the patients induced were belonged to the 20- 25 years group. Study of JANET et al (1999) SHARAMI(2005) showed that the maximum number of patients belonged to 20-30 years of age.

- Majority of the patients were PRIMI GRAVIDA. The study of JANET et al and GUINN et al(2004) also had maximum number of primi patients.

- Majority of the patients induced were between 40-41 weeks. The study of KARJANE et al(2006) also showed that post datism was the most common reason for induction.

CHANGE IN BISHOP SCORE

- Both the groups were induced with almost similar Bishop score initially. The mean Bishop score at 0 hrs was 2.26 in Primis induced with Extra amniotic saline infusion and PGE2 gel was 2.25

- The mean Bishop score at 6 hrs was 6.62 in Primis induced with Extra amniotic saline infusion whereas PGE2 gel was 5.51

- The mean Bishop score at 12 hrs was 9.27 in Primis induced with Extra amniotic saline infusion whereas PGE2 gel was 8.08

- The mean Bishop score at 6 hrs was 8.57 in Multis induced with Extra amniotic saline infusion whereas PGE2 gel was 6.91

- The mean Bishop score at 12 hrs was 10.40 in Multis induced with Extra amniotic saline infusion whereas PGE2 gel was 9.41

- Mean Bishop score improved in higher rate in Extra amniotic saline infusion group when compared to PGE2 gel group.

- The difference is statistically significant ($P<0.01$)

INDUCTION TO ACTIVE LABOUR INTERVAL

- Majority of the patients induced with Extra amniotic saline infusion established active labour within 6 hrs whereas in PGE2 gel active labour established in 6-12 hrs.

- The mean Induction active labour interval in Primis induced with Extra amniotic saline infusion was 6.35 hrs and in PGE2 gel group was 8.35 hrs.

- The mean Induction active labour interval in Multis induced with Extra amniotic saline infusion was 4.98 hrs and in PGE2 gel group was 6.55 hrs.

- The difference between the two groups were statistically significant.($P<0.01$)

- Extra amniotic saline infusion was found to be more effective in causing cervical ripening than PGE2 gel.

OXYTOCIN AUGMENTATION

- Oxytocin use in Extra amniotic saline infusion was only 43% whereas in PGE2 gel group was about 72%. More number of patients in the PGE2 gel group required oxytocin for further progress of labour.

- The difference is statistically significant ($P<0.01$)

INDUCITON TO DELIVERY INTERVAL

- Majority of the patients induced with the Extra amniotic saline infusion delivered within 12 hrs when compared to PGE2 gel.

- The mean Induction delivery interval in Primis induced with Extra amniotic saline infusion was 11.2 hrs and in PGE2 gel group was 13.35 hrs.

- The mean Induction delivery interval in Multis induced with Extra amniotic saline infusion was 9.30 hrs and in PGE2 gel group was 12.78 hrs.

- The difference between the two groups were statistically significant.($P<0.01$)

MODE OF DELIVERY

- LSCS rate was only 19% in Extra amniotic saline infusion group when compared to about 27% in the PGE2 gel group.

- 76% of patients delivered vaginally in the Extra amniotic saline infusion group whereas only 67% had labour natural in the PGE2 gel group.

- The difference in the mode of delivery was statistically significant ($P<0.01$)

INDICATION FOR CESAREAN DELIVERY

- Incidence of Cesarean delivery was significantly lower in the Extra amniotic saline infusion when compared to the PGE2 gel group.

- Incidence of failed induction was only 3% in the Extra amniotic saline infusion group whereas it was 6% in the PGE2 gel group.

- Incidence of fetal distress was only 12% in the Extra amniotic saline infusion group whereas it was 19% in the PGE2 gel group.

- BUCCELLATO et al (2000) reported that failure to progress and non-reassuring fetal heart rate were common cause for Cesarean deliveries.

- GUINN et al (2004) reported that fetal distress was the most frequent indication for Cesarean section.

- SHARAMI et al (2005) reported that cervical dystocia was the most common cause for Cesarean section.

FETAL OUTCOME

- ✓ Only 7% of neonates were admitted in NICU in Extra amniotic saline infusion group whereas it was about 12% in the PGE2 gel group.

- ✓ The common cause for admission was Birth asphyxia, meconium aspiration.

- ✓ GUINN et al reported no significant maternal or neonatal morbidities.

MATERNAL OUTCOME

- ✓ 6 patients had hyperstimulation in the PGE2 gel group. The patients were put in left lateral position. Oxygen was given by face mask & IV fluids were given. No hyperstimulation was seen in the Extra amniotic saline infusion group.
- ✓ Puperal pyrexia was comparable in both the groups.
- ✓ There was no technical difficulty in Foley catheter insertion.
- ✓ JANET et al reported technical difficulty in one patient because of cervix position.
- ✓ SCHREYER et al reported mild bleeding (6%) shortly after Foley catheter.
- ✓ SHERMAN et al reported rupture of membrane at the time of insertion (2%)

SUMMARY

- Improvement in Bishop score was more in the Extra amniotic saline infusion group when compared to PGE2 gel group. P<0.01

- Mean Induction to active labour interval (ILI) was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.P<0.01

- Mean Induction to delivery interval was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.P<0.01

- The Mean Induction to active labour interval (IDL) and Mean Induction to delivery interval were shorter in Multis of both groups as compared to Primis of both the groups.P<0.01

- Oxytocin usage was higher in the PGE2 gel group when compared to Extra amniotic saline infusion group P<0.01

- Regarding Age, Parity, Gestational age and the indication for induction there was no significant difference in both the groups.

- 76% of patients in the Extra amniotic saline infusion had labour natural when compared to 67% in the PGE2 gel.

- LSCS incidence was about only 19% in the Extra amniotic saline infusion when compared to 27% in the PGE2 gel group.

- Incidence of LSCS for failed induction in the Extra amniotic saline infusion was only 3% when compared to 6% in the PGE2 gel group.

- Hyperstimulation of uterus was higher in the PGE2 gel when compared to the Extra amniotic saline infusion.$P<0.01$

- Neonatal admissions were comparatively more in the PGE2 gel group than Extra amniotic saline infusion.

- Extra amniotic saline infusion was found to be more effective, cheaper and readily available method for cervical ripening and induction of labour.

CONCLUSION

- Cervical ripening was more effective in the Extra amniotic saline infusion group when compared to PGE2 group.
- Mean Induction to active labour interval (ILI) was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.
- Mean Induction to delivery interval (ILI) was shorter in the Extra amniotic saline infusion group when compared to PGE2 gel group.
- Oxytocin usage was lower in the Extra amniotic saline infusion group when compared to PGE2 gel group.
- Response to Multis are better than Primis in both the groups.
- Fetal and Maternal outcome were better in the Extra amniotic saline infusion group than PGE2 gel group.
- Extra amniotic saline infusion was found to be more effective, cheaper and readily available method for cervical ripening and induction of labour.

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Annexures

PROFORMA

NAME AGE IP. NO: UNIT

SOCIO-ECONOMIC STATUS :

BOOKED : YES/ NO

IMMUNISED : YES/NO

MENSTRUAL HISTORY : REGULAR / IRREGULAR

: LMP EDD

MARITAL HISTORY : MARRIED /UNMARRIED

OBSTETRICS HISTORY : G☐ P☐ L☐ A☐

: STILL BIRTH/ NEONATAL DEATH

: LCB

PRESENT PREGNANCY : CONFIRMED BY: HCG

: BIMANUAL

: USG

QUICKENING

PERSONAL HISTORY : SMOKER

: ALCOHOLIC

: MIXED DIET

PREVIOUS OBSTETRIC HISTORY : H/O POST DATISM

: H/O PIH

GENERAL EXAMINATION : HEIGHT :
WEIGHT :

ANEMIA YES/ NO

FEBRILE YES/NO

EDEMA YES/ NO

TEMPERATURE : PULSE : BP :

CVS : RS :

OBSTETRIC EXAMINATION

PER ABDOMEN : UTERUS SIZE: < 37 WKS

TERM

ACTING / NOT ACTING

PRESENTATION : CEPHALIC / NON-CEPHALIC

PRESENTING PART : UNENGAGED / ENGAGED

FOETAL HEART RATE :

PELVIC EXAMINATION

CERVICAL EFFACEMENT : 0 ☐ 25 ☐ 50 ☐ 75 ☐ 100 ☐

POSITION : ANT. ☐ MIDDLE ☐ POST. ☐

CONSISTENCY : FIRM ☐ MEDIUM ☐ SOFT ☐

DILATATION : 0 ☐ 1-2 ☐ 3-4 ☐ 5-6 ☐

STATION : -3 ☐ -2 ☐ -1, 0 ☐ +1,+2,+3 ☐

BISHOP SCORE : 0 HOURS ☐

6 HOURS ☐

12 HOURS ☐

18 HOURS ☐

24 HOURS ☐

INVESTIGATIONS : URINE ALB ☐ SUGAR ☐ DEP. ☐

BLOOD UREA SUGAR

ELECTROLYTES: / / / /

CTG : REACTIVE ☐ NON-REACTIVE ☐

USG : SINGLETON ☐ MULTIPLE ☐

VERTEX ☐ NON VERTEX ☐

GA : < 40 ☐ 40-41 ☐ 41-42 ☐ > 42 ☐

AFI: <5 ☐ 5-10 ☐ > 10 ☐

PLACENTA : FH

INDICATION FOR INDUCTION : POST EDD

PIH

IUD

OLIGOHYDRAMNIOS

PROM

OTHERS

MODE OF INDUCTION : CERVIPRIME GEL ☐

CERVICAL BALLOON DILATATION WITH EASI ☐

OXYTOCIN USED ☐ NOT USED ☐

INDUCTION TO ACTIVE LABOUR INTERVAL :

INDUCTION TO DELIVERY INTERVAL :

DURATION OF LABOUR : I STAGE
II STAGE

MONITORING INTRAPARTUM MATERNAL & FETAL CONDITIONS:

MATERNAL : TEMP: PR: BP: HYDRATION:

FETAL : FHR: MECONIUM:

MODE OF DELIVERY

LABOUR NATURAL ☐

FORCEPS ☐

VACUUM ☐

LSCS ☐

INDICATION FOR LSCS :

FAILED INDUCTION ☐

FETAL DISTRESS ☐

SEVERE PIH ☐

CPD ☐

CERVICAL DYSTOCIA ☐

OTHERS ☐

COMPLICATION DURING LABOUR :

BABY DETAILS : WEIGHT SEX

APGAR : 1 MIN ☐ 5 MIN ☐

ADMISSION YES / NO

PRETERM / TERM /AGA /SGA / IUGR

CONGENITAL ANOMALIES: YES / NO

COMPLICATIONS :

MATERNAL -

INTRAPARTUM - MATERNAL DISTRESS : YES / NO

PPH : YES/ NO

PYREXIA : YES / NO

POSTPARTUM : EPISIOTOMY WOUND SEPSIS : YES / NO

- PYREXIA : YES / NO

Master Chart

S No.	Name	IP.No.	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	Oxy.	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
1	Mythili	8032	25	3	37	4	2	6	11		0	0	7.5	12	0		good	0	0	0	0
2	Valarmathy	12091	26	1	41	2	3	6	8		0	1	9	10	1	0	good	0	0	0	0
3	Maarthal	12013	26	1	41	1	1	4	7		0	1	8	9	1	0	adm	0	0	0	0
4	Saraswathy	12085	21	1	40	1	2	6	9		0	1	9	13	1	0	good	0	0	0	0
5	Sumathy	12134	25	2	40	1	3	7	10		0	0	5.5	12	0		good	0	0	0	0
6	Megala	11552	22	2	40	1	3	9			0	0	5.5	10	0		good	0	0	0	0
7	Bhuvaneswari	12199	22	2	41	1	3	8	10		0	0	5.5	12	0		good	0	0	0	0
8	Vijayalajshmi	12064	19	2	41	1	2	7	10		0	0	6	14	0		good	0	0	0	0
9	Abirami	12069	20	3	41	1	2	7	10		0	0	6	14	0		good	0	0	0	0
10	Gowri	12054	23	2	40	1	2	4	7		0	0	10	13.5	1	3	good	0	0	0	0
11	Bharathi	11987	22	1	41	2	3	6	8	12	0	1	8	20	0		adm	1	0	0	0
12	Chitra	12181	21	1	41	1	3	6	8		0	1	9	10	1	0	good	0	0	0	0
13	Saritha	12057	20	2	41	1	3	8	11		0	0	5.5	12	0		good	0	0	0	0
14	Punitha	12175	28	1	40	1	2	4	8		0	1	11	13	1	0	good	0	0	0	0
15	Maria	12356	23	2	40	1	3	10			0	0	5.5	10	0		good	0	0	0	0
16	Fathima	12399	27	1	41	1	2	6	10		0	1	5.5	12	0		adm	0	0	0	0
17	Poornima	12452	21	2	41	1	3	8	10		0	0	5.5	12	0		good	0	0	0	0
18	Pushpa	12350	29	2	41	1	2	8	10		0	0	6	14	0		good	0	1	0	0
19	Maragatham	12598	20	3	41	1	2	7	10		0	0	6	14	0		good	0	0	0	0
20	Malarvizhi	12519	20	3	40	1	3	6	8	10	0	0	8	12	1	0	good	0	0	0	0
21	Devi	12158	21	2	37	4	2	6	10		0	0	7.5	12	0		adm	0	0	0	0
22	Amala	12327	22	1	41	1	3	6	8		0	1	9	10	1	0	good	0	0	0	0
23	Annapoorni	12470	26	2	40	1	3	9	11		0	0	5.5	12	2		good	0	0	0	0
24	Ameena	12604	22	1	41	1	2	6	7	11	0	1	7.5	14	0		adm	0	0	0	0
25	Mangayarkarasi	7918	30	2	40	1	3	9	11		0	0	5.5	12	0		good	0	0	0	0

S No.	Name	IP.No.	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	Oxy.	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
26	Sulochana	7569	30	2	40	1	3	9			0	0	5.5	10	0		good	0	0	0	0
27	Lidial	12127	25	1	40	1	2	6	9		0	1	7	13	1	0	good	0	0	1	1
28	Shahidabegum	12228	24	3	41	5	2	7	10		0	0	6	14	0		good	0	0	0	0
29	Sandhya	10817	23	1	41	1	3	8	11		0	1	6	11	0		adm	1	0	0	0
30	Lakshmi	10740	28	1	41	1	1	4	9		0	0	8.5	11.5	0		good	0	0	0	0
31	Naseemabanu	10892	21	1	40	1	3	5	8		0	1	8.5	13.5	1	0	good	0	0	0	0
32	Jeya	11056	22	2	41	5	3	7	11		0	0	5.5	12	2		good	0	0	0	0
33	Katheeja	11074	24	1	41	1	1	4	7		0	1	8	9	1	0	adm	0	0	0	0
34	Maheswari	11141	28	3	40	1	3	8	9		0	0	6	16	0		good	0	1	0	0
35	Mala	27438	22	1	41	2	2	7	10		0	1	5.5	11	0		adm	0	0	0	0
36	Shoba	27445	20	1	40	1	2	4	8		0	1	11	13	1	0	adm	0	0	0	0
37	Ponni	27297	22	1	41	4	0	4	7	12	0	1	13	19	1	5	adm	1	0	1	1
38	Renuka	27769	33	1	41	1	1	5	9		0	0	8.5	11.5	0		good	0	0	0	0
39	Vijayalakshmi	27602	20	1	41	1	1	4	7	12	0	1	13	19	1	0	adm	0	0	1	0
40	Suguna	27770	18	1	40	1	3	4	8	10	0	1	10	19	1	0	adm	1	0	0	0
41	Devi	27670	17	3	38	2	1	4	4		0	1		9	1	1	adm	0	1	0	0
42	Gnanambigai	27664	19	2	37	4	2	6	10		0	0	7.5	12	0		good	0	0	0	0
43	Seetha	27985	27	3	40	1	3	7	11		0	0	6	12	0		good	0	0	0	0
44	Selvapunitha	27847	31	2	40	1	3	4	8	10	0	1	10	19	1	5	adm	0	0	0	0
45	Mala	27838	22	5	40	1	3	9	12		0	0	5.5	12	0		good	0	0	0	0
46	Priya	27540	22	2	40	1	3	8	11		0	0	5.5	12	0		good	0	0	0	0
47	Revathy	27682	25	2	40	1	3	7	11		0	0	5.5	12	2		adm	0	0	0	0
48	Kannagi	28038	33	3	41	1	2	7	9		0	0	6	16	0		good	0	0	0	0
49	Kalavathy	28018	24	2	40	1	3	7	10		0	0	6	12	0		adm	1	0	0	0
50	Dilli	27835	26	1	41	1	1	3	7	12	0	1	13	19	1	0	adm	0	0	1	1

S No.	Name	IP.No.	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	Oxy.	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
51	Sumathy	27921	27	2	41	1	2	7	10		0	0	6	14	0		good	0	1	0	0
52	Reshmasultana	33987	22	1	41	1	2	7	9		0	1	6.5	12	0		good	0	0	0	0
53	Amudha	34317	21	2	41	1	4	10			0	0	6	9	0		good	0	0	0	0
54	Mahalakshmi	34423	23	1	40	1	2	5	7	12	0	1	9	16	0		good	0	0	0	0
55	Tamilselvi	12153	26	1	40	1	2	5	7	11	0	1	7.5	19	0		good	0	0	0	0
56	Prema	12163	21	1	41	1	2	6	8	11	0	1	7.5	14	0		good	0	0	0	0
57	Devi	12161	21	1	41	1	2	7	10		0	1	6.5	12	0		good	0	0	0	0
58	Madeena	12221	25	1	41	2	3	6	8	12	0	1	8	20	0		good	0	0	0	0
59	Latha	12243	22	1	41	2	3	6	7	12	0	1	8	20	0		good	1	0	0	0
60	Manjula	12244	18	1	40	1	2	4	7	12	0	1	9	16	0		good	0	0	0	0
61	Nalini	12087	30	1	41	1	2	7	9		0	1	6.5	12	0		good	0	0	0	0
62	Jabarar	12288	23	1	40	1	2	5	7	12	0	1	9	16	0		good	0	0	0	0
63	Saraswathi	12157	24	5	42	1	4	9			0	0	6	9	0		good	0	0	0	0
64	Salma	12401	28	1	41	2	3	6	9	12	0	1	8	20	0		good	0	0	0	0
65	Lalitha	12433	33	1	40	1	2	5	7	12	0	1	9	16	0		good	0	0	0	0
66	Usha	12459	22	1	41	1	2	7	10		0	1	6.5	12	0		good	0	0	0	0
67	Nachamma	12494	25	1	41	2	3	6	8	12	0	1	8	20	0		good	0	0	0	0
68	Sheela	12512	26	3	41	1	2	7	10		0	1	5.5	11	0		good	0	0	0	0
69	Prema	12451	22	1	40	1	2	5	7	11	0	1	7.5	19	0		good	0	0	0	0
70	Saridha	12620	20	1	40	1	2	5	8	11	0	1	7.5	19	0		good	0	1	0	0
71	Gomathy	12479	21	1	40	1	2	4	7	11	0	1	7.5	19	0		good	0	0	0	0
72	Usha	12522	28	1	40	1	2	4	7	12	0	1	9	16	2		good	0	0	0	0
73	Perimma	12521	30	1	41	1	2	7	9		0	1	6.5	12	0		good	0	0	0	0
74	Sumathy	12535	25	1	40	1	2	5	7	12	0	1	9	16	0		good	0	0	0	0
75	Chithra	12506	25	1	40	1	2	5	7	12	0	1	9	16	2		good	0	0	0	0

S No.	Name	IP.No.	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	Oxy.	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
76	Jothilakshmi	12601	20	4	42	1	4	9			0	0	6	9	0		good	0	0	0	0
77	Anuradha	12554	25	1	41	1	2	6	8	11	0	1	7.5	14	0		good	0	0	0	0
78	Amudha	10856	23	1	41	1	2	6	8	11	0	1	7.5	14	0		good	0	0	0	0
79	Mythili	10866	27	1	41	2	3	6	7	12	0	1	8	20	0		good	0	0	0	0
80	Thagira	10970	21	1	38	2	3	6	7	12	0	1	8	20	0		good	0	0	0	0
81	Roopkala	10971	23	1	40	1	2	4	7	11	0	1	7.5	19	0		good	0	0	0	0
82	Sujatha	12464	20	1	41	1	3	4	7		0	1	8	14	1	3	good	0	0	0	0
83	Kameswari	12631	24	1	41	1	1	5	10		0	0	8.5	11.5	0		good	0	0	0	0
84	Mercy	12700	21	1	41	1	3	4	7		0	1	8	14	1	0	good	0	0	0	0
85	Nalini	12593	25	1	41	1	1	5	10		0	0	8.5	11.5	0		good	0	0	0	0
86	Lakshmi	11143	20	1	41	1	3	8	11		0	1	6	11	0		good	0	0	0	0
87	Punitha	11105	24	1	41	1	2	7	11		0	1	5.5	12	0		good	0	0	0	0
88	Sundari	10723	24	1	41	4	1	3	3		0	1		12	1	1	good	0	0	0	0
89	Padmavathy	11136	23	1	41	1	2	7	10		0	1	5.5	11	0		good	0	0	0	0
90	Sasikala	11286	22	1	41	1	3	8	10		0	1	6	11	0		good	0	0	0	0
91	Rajinamary	11284	22	1	40	1	2	6	9		0	1	7	13	1	5	good	0	0	0	0
92	Geetha	12451	21	1	41	1	3	6	7	11	0	1	11	20	1	0	good	1	0	0	0
93	Sivasakthi	12290	20	1	40	1	2	5	7		0	1	10	13.5	1	0	good	0	0	0	0
94	Sujana	12537	20	1	40	1	2	3	3		0	1		13.5	1	1	good	0	0	0	0
95	Ganga	12523	21	1	41	1	3	8	11		0	1	6	11	0		good	0	0	0	0
96	Sumithra	12336	25	1	41	1	2	6	11		0	1	5.5	12	0		good	0	0	0	0
97	Usha	12548	27	1	42	1	3	4	5		0	1		13	1	1	good	0	0	0	0
98	Kavitha	12275	22	1	41	1	2	7	9		0	1	5.5	11	0		good	0	0	0	0
99	Suganthi	12443	20	1	41	1	3	8	10		0	1	6	11	0		good	0	0	0	0
100	Vadivukarasi	12381	20	1	41	1	3	4	5		0	1		14	1	1	good	0	0	0	0

Master Chart

S.No.	Name	IP no	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	OXY	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
1	Valli	8367	23	2	40	1	3	7			1	0	6	9.5	0		good	0	0	0	0
2	valarmathy	11126	24	2	41	1	2	8			1	0	4	11	0		good	0	0	0	
3	mahalakshmi	21595	23	2	40	1	3	10			1	0	4	8	0		good	0	0	0	0
4	Ameena	13862	24	1	40	1	3	8	12		1	1	6	13	0		good	0	0	0	0
5	sudha	13894	26	1	41	1	2	5	12		1	1	7	13	0		good	0	0	0	0
6	Bharathi	34250	26	1	40	1	2	7			1	0	4.5	9	0		good	0	0	0	0
7	Shakila	8046	23	1	38	2	2	8			1	0	7	11	0		adm	0	1	0	0
8	Pasamalar	10883	20	1	40	1	2	5	10		1	1	7	12	1	0	good	0	0	0	0
9	Dhanalakshmi	21949	24	1	41	1	2	4			1	1		13	1	1	good	0	0	0	0
10	Rani	34328	20	1	40	1	3	8			1	0	5.5	8	0		good	0	0	0	0
11	Anjalai	34332	21	1	40	1	3	8			1	0	4	8	0		good	0	0	0	0
12	Karpagam	34366	21	1	38	1	3	8			1	0	5	11	0		good	0	0	0	0
13	Sasikala	34377	20	1	40	1	2	9			1	0	5	10	0		good	0	0	0	0
14	Bhuvana	34266	29	2	40	1	3	9			1	0	4	7	0		good	0	0	0	0
15	latha	22017	29	1	40	1	3	5	12		1	1	7	12	0		good	0	0	0	0
16	Sivakumari	13898	32	3	40	1	4	9			1	0	5	8	0		good	0	0	0	0
17	Selvarani	22081	22	1	40	1	2	5	8		1	1	6	11	0		good	0	0	0	0
18	Jayanthi	22084	23	1	41	1	3	7			1	0	5	9	0		good	0	0	0	0
19	Jamuna	21637	25	1	41	1	2	4	7	11	1	1	10	19	1	0	good	0	0	1	1
20	Maheswari	13909	22	1	40	1	4	6	9		1	1	5	10	0		good	0	0	0	0
21	Asaraba	22108	20	2	40	4	3	6	11		1	1	6	14	0		adm	0	0	0	0
22	Seetha	22130	21	2	40	1	3	9			1	0	4	8	0		good	0	0	0	0
23	Jesintha	22119	22	4	41	5	4	9			1	0	3	9	0		good	0	0	0	0
24	Devi	22043	21	1	41	1	2	8			1	0	5	9	0		good	0	0	0	0
25	Durga	22047	22	1	40	1	1	4	8		1	1	8	14	1	0	good	0	0	0	0

S.No.	Name	IP no	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	OXY	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
26	Lakshmi	21788	26	1	41	1	3	8			1	0	5	8.5	0		good	0	0	0	0
27	Vimala	22039	21	1	40	1	1	6	12		1	1	5	10	0		good	0	0	0	0
28	Stella mary	21984	22	2	40	1	1	6	11		1	1	5	12	0		good	0	0	0	0
29	Dhanalakshmi	10933	19	2	40	2	3	10			1	0	5	8	0		good	0	0	0	0
30	Devi	22059	24	2	40	1	3	10			1	0	6	8	0		good	0	0	0	0
31	Amudha	23626	22	1	38	4	1	6	11		1	1	7.5	13	0		good	0	0	0	0
32	Vijaya	23639	24	1	40	1	1	6	10		1	1	7.5	13.5	0		good	0	0	0	0
33	Kasthuri	23511	30	1	41	1	2	6	12		1	1	6	12.5	2		good	0	0	0	0
34	Barkathnisha	23589	26	1	41	1	2	7			1	0	5	8.5	0		good	0	0	0	0
35	Sumathy	23630	22	1	40	1	2	7			1	0	4	7.5	0		good	0	0	0	0
36	Ambika	23615	32	1	40	1	2	8			1	0	6	9.5	0		good	0	0	0	0
37	Sathya	23621	21	1	40	1	2	7			1	0	5	8.5	0		good	0	0	0	0
38	Karpagam	23614	22	2	41	1	3	10			1	0	4.5	9	0		good	0	0	0	0
39	Fathima	23124	27	1	40	1	3	8			1	0	6	8	1	3	adm	0	0	0	0
40	Sundari	23623	29	1	40	4	1	4	6		1	1	8	12	1	5	good	0	0	0	0
41	Saranya	23603	25	1	40	1	3	8			1	0	4.5	8.5	0		good	0	0	0	0
42	Mumtaz	23573	18	1	40	1	3	8			1	0	5.5	7	0		good	0	0	0	0
43	Geetha	12451	21	1	40	1	3	8			1	0	5	9.5	0		good	0	0	0	0
44	Vijayalakshmi	23496	20	1	37	2	1	4	6		1	1	12	13	1	2	good	0	1	0	0
45	chitra	23153	26	1	41	1	1	5	11		1	1	7	13	0		good	0	0	0	0
46	Banu	23580	19	1	38	2	3	8			1	0	4	8	0		adm	0	1	0	0
47	Gowri	23594	20	1	40	1	1	6	11		1	1	6	14	0		good	0	0	0	0
48	Maragatham	23598	23	3	40	2	3	8			1	0	5	8	0		good	0	0	0	0
49	Kanchana	23593	27	3	40	1	3	8			1	0	4	7	0		good	0	0	0	0
50	Sivashankari	23592	30	1	40	1	1	4	8		1	1	8	14	1	0	good	0	0	0	0

S.No.	Name	IP no	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	OXY	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
51	Parimala	23584	23	1	41	1	2	7			1	0	5.5	9	0		good	0	0	0	0
52	Susheela	34312	29	1	40	2	3	7			1	0	6.5	8.5	1	0	good	0	0	1	0
53	Shanthy	34348	22	1	37	2	3	8			1	0	6	9.5	0		good	0	0	0	0
54	Anjalai	34332	21	1	41	1	2	8			1	0	6	11	0		good	0	0	0	0
55	Gnanaoli	34340	26	1	40	1	2	4	6		1	1	11	12	1	0	good	0	0	0	0
56	Vimala	7920	24	1	40	5	3	8			1	0	5.5	8	1	0	good	0	0	0	0
57	Jacqulin	34333	21	1	41	1	2	5			1	1	6	7	1	3	good	0	0	0	0
58	Saritha	7881	20	1	40	1	3	8			1	0	4.5	8.5	0		good	0	0	0	0
59	Jayalakshmi	7888	22	1	40	1	1	5	11		1	1	6.5	13	0		good	0	0	0	0
60	Devi	16234	30	3	40	1	2	7			1	0	5.5	8.5	0		good	0	0	0	0
61	Mala	34368	22	3	40	1	3	11			1	0	4	7	0		good	0	0	0	0
62	Revathy	7853	18	1	40	1	3	8	10		1	1	5.5	13	0		good	0	0	0	0
63	Parveen	7947	20	2	38	2	4	9			1	0	4.5	9	0		adm	0	0	0	0
64	Ramani	34362	20	2	40	1	4	9			1	0	4.5	7.5	0		good	0	0	0	0
65	Porkodi	34388	25	3	40	1	3	8			1	0	5	9.5	0		good	0	0	0	0
66	Lakshmi	7828	20	1	41	1	3	9			1	0	4.5	11	0		good	0	0	0	0
67	Dhanalakshmi	16719	24	1	37	1	2	8			1	1	6.5	7	1	3	good	0	0	0	0
68	Subbulaxmi	7366	25	1	40	1	3	6	9	12	1	1	7.5	18	0	3	good	0	0	1	1
69	Jaya	34420	21	1	40	1	2	8			1	0	5.5	11.5	0		good	0	0	0	0
70	Sridevi	22050	23	2	42	1	3	9			1	0	5.5	9.5	0		good	0	0	0	0
71	Amudha	8092	20	1	40	1	2	8	11		1	1	5.5	13.5	0		good	0	0	0	0
72	Manjula	8094	20	1	40	1	3	8	11		1	1	5.5	13	0		good	0	0	0	0
73	Revathy	16338	21	1	40	5	1	4	8		1	1	12	13	1	3	good	0	0	0	0
74	Saraswathy	7574	18	1	40	1	2	8	11		1	1	5	13	0		good	0	0	0	0
75	Kamatchi	22201	25	2	41	1	3	9			1	0	5.5	11	0		good	0	0	0	0

S.No.	Name	IP no	Age	Gravida	US	IFI	BS 0	BS 6	BS 12	BS 18	MOI	OXY	ILI	IDI	MOD	Ind-CS	NO	Int. MD	Int. PPH	Int. Pyr.	Post. Sep.
76	Kanchana	7555	24	2	40	4	2	6	11		1	1	6.5	12	0		adm	0	0	0	0
77	Krishnaveni	33316	25	4	40	1	3	8	12		1	1	5.5	12	0		good	0	0	0	0
78	Petrisha	7654	27	1	40	1	4	10			1	0	3.5	8	0		good	0	0	0	0
79	Yeshoda	13452	22	2	40	5	3	8			1	0	4	10	0		good	0	0	0	0
80	Latha	22017	22	2	41	1	3	10			1	0	6	11	0		good	0	0	0	0
81	Sooryakala	34521	27	2	41	1	4	10			1	0	4.5	8	0		good	0	0	0	0
82	Saradevi	12119	27	1	40	1	3	8	11		1	1	5	13	0		good	0	0	0	0
83	Jeya	11056	22	1	40	1	2	4	6		1	1	12	13	1	0	good	0	0	0	0
84	Kamatchi	34270	30	3	40	1	4	9			1	0	5	12	0		good	0	0	0	0
85	Banu	34372	23	2	38	1	3	10			1	0	4.5	8.5	0		good	0	0	0	0
86	Seethalakshmi	22019	28	2	41	5	3	9			1	1	6	9	0		good	0	0	0	0
87	Lakshmi	34421	21	2	41	1	3	9			1	0	6	9	0		good	0	0	0	0
88	Hemavathy	34521	24	2	41	1	2	10			1	0	4	9	0		good	0	0	0	0
89	Mallika	11934	23	2	41	1	3	8			1	0	4	8	0		good	0	0	0	0
90	Lakshmi	11915	23	3	41	1	2	7			1	0	4	8	0		good	0	0	0	0
91	Amudha	12226	22	3	41	1	2	7			1	0	5.5	11	0		good	0	0	0	0
92	Akilandam	12354	28	1	40	1	3	8			1	0	4.5	9	0		good	0	0	0	0
93	Rajeswari	34376	21	2	38	2	3	8			1	0	7	11	0		adm	0	1	0	0
94	Kumari	10974	23	2	41	4	2	5	7		1	1	7	12	1	0	good	0	0	0	0
95	Devi	16838	22	1	40	1	2	8	11		1	1	5	13	0		good	0	0	0	0
96	Geetha	12213	26	1	41	1	3	8			1	0	5.5	8	0		good	0	0	0	0
97	Devika	11979	24	2	41	1	3	9			1	0	4	8	0		good	0	0	0	0
98	Sudha	16559	28	1	38	4	1	5	8		1	1	6	14	2		good	0	0	1	0
99	Nagammal	23344	30	1	40	1	3	9			1	0	5	10	0		good	0	0	0	0
100	Uma maheswari	14779	25	1	40	1	2	6			1	0	6	8.5	1	0	good	0	0	0	0

CODING

Age	in years		
MH	Menstrual History	Regular	1
		Irregular	0
GRAVIDA	Obstetric Formula	Primi	1
		Second	2
		Third	3
US	Uterus Size in weeks		
IFI	Indication for Induction	Post EDD	1
		PIH	2
		IUD	3
		Oligohydramnios	4
BISHOP SCORE	0 HRS	BS O	
	6 HRS	BS 6	
	12 HRS	BS 12	
	18 HRS	BS 18	
MOI	Mode of Induction	Cerviprime	0
		Balloon Dilatation	1
OXY	Oxytocin	Used	1
		Not used	0
Lab. Int.	Labour Interval	in hours	ILI
Del. Int.	Delivery Interval	in hours	IDI
MOD	Mode of Delivery	Lab. Natural	0
		LSCS	1
		Forceps	2
		Vacuum	3

Ind. For LSCS	Indication for LSCS	Fetal distress	0
		Failed induction	1
		Severe PIH	2
		CPD	3
		Cervical Dystocia	4
		Others	5

NEONATAL OUTCOME			GOOD	ADM
Int. MD	Intrapartum	Maternal Distress	Yes	1
			No	0
Int. PPH	Intrapartum	PPH	Yes	1
			No	0
Int. Pyrexia.	Intrapartum	Pyrexia	Yes	1
			No	0
Post. Sep.	Postpartum	Sepsis	Yes	1
			No	0
Post. Pyrexia.	Postpartum	Pyrexia	Yes	1
			No	0

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI-3

EC Reg No.ECR/270/Inst./TN/2013
Telephone No. 044 25305301
Fax : 044 25363970

CERTIFICATE OF APPROVAL

To
Dr. V. Vijayalakshmi,
Postgraduate M.D.(Obstetrics & Gynaecology),
Madras Medical College/Institute of Obstetrics & Gynaecology,
Chennai – 600 008.

Dear Dr. V.Vijayalakshmi,

The Institutional Ethics Committee has considered your request and approved your study titled **"Comparative study of extra-amniotic saline infusion through intracervical balloon catheter and prostaglandin E2 GEL for induction of labour " No.11092014.**

The following members of Ethics Committee were present in the meeting held on 02.09.2014 conducted at Madras Medical College, Chennai-3.

1. Dr.C.Rajendran, M.D.,	: Chairperson
2. Dr.R.Vimala, M.D., Dean, MMC, Ch-3	: Deputy Chairperson
3. Prof.B.Kalaiselvi, M.D., Vice-Principal, MMC, Ch-3	: Member Secretary
4. Prof.R.Nandhini, M.D., Inst.of Pharmacology, MMC	: Member
5. Dr.G.Muralidharan, Director Incharge, Inst.of Surgery	: Member
6. Prof.K.Ramadevi, Director i/c, Inst.of Biochemistry, MMC	: Member
7. Prof.Saraswathy, M.D., Director, Pathology, MMC, Ch-3	: Member
8. Prof.Tito, M.D., Director i/c, Inst.of Internal Medicine, MMC	: Member
9. Thiru S.Rameshkumar, Administrative Officer	: Lay Person
10. Thiru S.Govindasamy, B.A., B.L.,	: Lawyer
11. Tmt.Arnold Saulina, M.A., MSW.,	: Social Scientist

We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary, Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

INFORMATION SHEET

TITLE: COMPARATIVE STUDY OF EXTRA AMNIOTIC SALINE INFUSION THROUGH INTRACERVICAL BALOON CATHETER AND PROSTAGLANDIN E2 GEL FOR INDUCTION LABOUR.

Investigator:

Name of the Participant:

This study is conducted in Institute of Obstetrics and Gynecology, Egmore, Chennai. You are invited to take part in this study. The information in this documents is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns.

Purpose of the study

We are conducting a study on induction of labour by comparing extra amniotic saline instillation method and prostaglandin gel. The purpose of this study is to identify better and effective method for induction of labour.

The study design and procedure

All pregnant mothers in the study will be divided into 2 groups. You will be assigned to either of the groups. One group will be induced with extra amniotic saline infusion and other will be induced in the prostaglandin E2 gel you will be monitor till the delivery.

Possible Benefits

The results of the research may provide benefits to future pregnant mothers for better and effective method for induction of labour.

Confidentiality of the information obtained from you

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Can you decide to stop participating in the study once you start?

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits.

The results of the special study may be intimated to you at the end of the study period.

Signature of Investigator **Signature of Participant**

Date :

ஆராய்ச்சி தகவல் தாள்

ஆராய்ச்சி தலைப்பு

நிறைமாத கர்ப்பிணி பெண்களுக்கு பனிகுடம் வெளிபுறம் உப்புநீர் கரைசல் செலுத்துதல் அல்லது PGE2 ஜெல் மருந்து வைத்து பிரசவ வலித்தூண்டுதல் ஒப்பீட்டு ஆய்வு

ஆய்வாளர் :

பங்கேற்பாளர் :

இந்த ஆய்வு எழும்பூர், தாய்சேய் நல மகப்பேறு அரசு மருத்துவமனையில் நடைபெற உள்ளது. நீங்களும் இந்த ஆய்வில் பங்கேற்க நாங்கள் விரும்புகிறோம். இதிலுள்ள தகவலின் அடிப்படையில் இந்த ஆய்வில் பங்கேற்பதா அல்லது வேண்டாமா என்று நீங்கள் முடிவு செய்து கொள்ளலாம். உங்களது சந்தேகங்களை எங்களிடம் கேட்டு நிவர்த்தி செய்து கொள்ளலாம்.

இந்த ஆய்வின் நோக்கம்:

நிறைமாத கர்ப்பிணி பெண்களுக்கு பிரசவ வலி தூண்டலுக்கு பனிகுடம் வெளிபுறம் உப்புநீர் கரைசல் செலுத்துதல் அல்லது PGE2 ஜெல் மருந்து வைத்தல் – இரண்டுமுறையும் ஒப்பிடுதல் என்பதே இந்த ஆராய்ச்சி நோக்கம்.

ஆய்வின் செயல்முறை:

இந்த ஆய்வில் கலந்து கொள்பவர்கள் இரண்டு குழுக்களாக பிரிக்கப்படுவீர். முதல் குழுவில் இருப்பவர்கள் பிரசவ வலி தூண்டலுக்கு பனிகுடம் வெளிபுறம் உப்புநீர் கரைசல் செலுத்தப்படுவர். இரண்டாவது குழுவில் உள்ளவர்கள் ஜெல் மருந்து வைத்து பிரசவ வலி தூண்டுதல் செய்யப்படுவர்.

தங்களுக்கு இவ்விரண்டில் ஏதேனும் ஒரு முறையில் பிரசவ வலி தூண்டல் செய்து பிரசவம் வரையில் கண்காணிக்கப்படுவீர்.

ஆய்வினால் ஏற்படும் நன்மைகள்:

வருங்காலத்தில் பிறநோயாளிகளுக்கு பிரசவ வலித்தூண்டலுக்கு மிக எளிமையான பயனுள்ள அணுகூலமான எதிர்விளைவு குறைவாக உள்ள முறையை அறிய முடியும்.

மருத்துவ சிகிச்சையின் தகவல்கள் குறித்த விவரங்கள்:

உங்கள் மருத்துவ சிகிச்சை குறித்த தகவல்கள் ரகசியமாக பாதுகாக்கப்படும்.

நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இந்த ஆராய்ச்சியில் உங்களுக்கு பரிசோதனைகள் செய்து அதன் தகவல்களை ஆராய்வோம்.

அதனால் தங்களது நோயின் ஆய்வறிக்கையோ அல்லது சிகிச்சையோ பாதிப்பு ஏற்படாது என்பதையும் தெரிவித்துக்கொள்கிறோம்.

முடிவுகளை அல்லது கருத்துகளை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின் போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின் பேரில் தான் இருக்கிறது. மேலும் நீங்கள் எந்நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

இந்த சிறப்பு சிகிச்சையின் முடிவுகளை ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின் போது தங்களுக்கு அறிவிக்கப்படும் என்பதையும் தெரிவித்துக் கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

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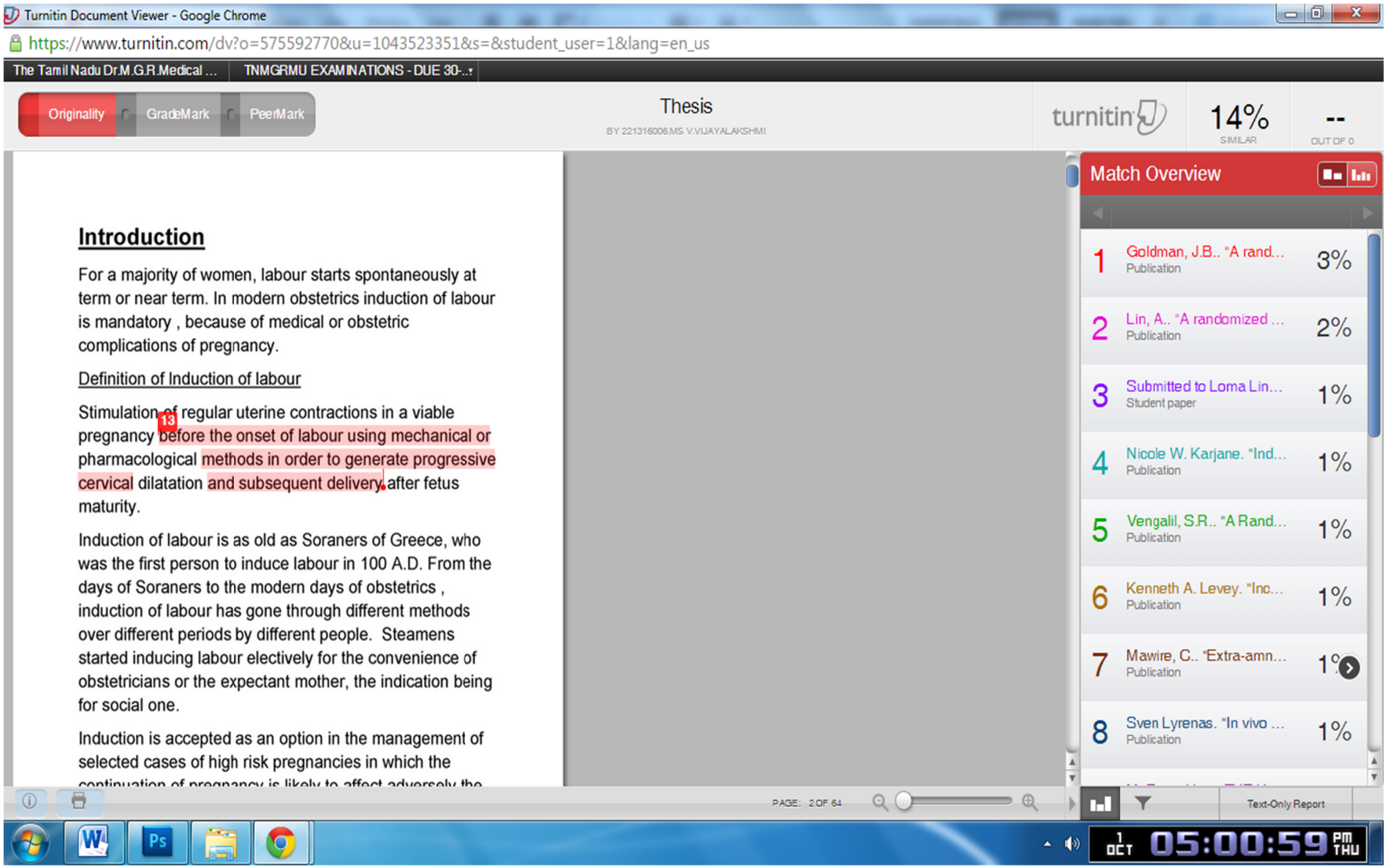
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Introduction
For a majority of women, labour starts spontaneously at term or near term. In modern obstetrics induction of labour is mandatory , because of medical or obstetric complications of pregnancy.
Definition of Induction of labour
Stimulation of regular uterine contractions in a viable pregnancy before the onset of labour using mechanical or pharmacological methods in order to generate progressive cervical dilatation and subsequent delivery after fetus maturity.
Induction of labour is as old as Soraners of Greece, who was the first person to induce labour in 100 A.D. From the days of Soraners to the modern days of obstetrics , induction of labour has gone through different methods over different periods by different people. Steamens started inducing labour electively for the convenience of obstetricians or the expectant mother, the indication being for social one.
Induction is accepted as an option in the management of selected cases of high risk pregnancies in which the
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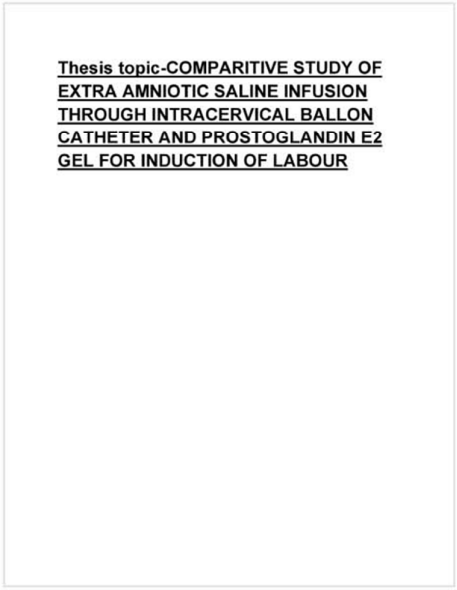

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